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医药卫生法律资讯

Health Care Legal Newsletter

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大成律师事务所
医药卫生法律研究团队

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The Guiding Opinions on Promoting and Regulating the Application and Development of Big Data on Health and Medical Treatment

1. 颁布详情 Enacted details

1) 颁布部门 Promulgated authority:The General Office of the State Council
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2. 跟踪报道 Related content

2016 年 6 月 21 日，国务院办公厅印发《关于促进和规范健康医疗大数据应用发展的指导意见》（下称《意见》）。

《意见》提出，到 2020 年，建成国家医疗卫生信息分级开放应用平台，依托现有资源建成 100 个区域临床医学数据示范中心，基本实现城乡居民拥有规范化的电子健康档案和功能完备的健康卡，适应国情的健康医疗大数据应用发展模式基本建立，健康医疗大数据产业体系初步形成等。据此，《意见》从夯实应用基础、全面深化应用、规范和推动“互联网+健康医疗”服务、加强保障体系建设等四方面部署了 14 项重点任务和重大工程。其中，《意见》明确，建设统一权威、互联互通的人口健康信息平台；推动健康医疗大数据资源共享开放；推进健康医疗行业治理、临床和科研以及公共卫生的大数据应用等。

The General Office of the State Council has issued the Guiding Opinions on Promoting and Regulating the Application and Development of Big Data on Health and Medical Treatment (the "Opinions") on June 21,2016.

The Opinions note that by 2020, a national platform for the classification, disclosure and application of health care information will be established; 100 regional demonstration centers for clinical data be set up based on the existing resources; the possessing of normalized electronic health records and care cards of full functions by urban and rural residents be basically realized; the model of application and development of big data on health and medical treatment adaptive to the national conditions be basically built; and the industrial system for big data on health and medical treatment be primarily formed. Accordingly, the Opinions make deployments for 14 key tasks and major projects from four aspects, namely, consolidating the application basis, comprehensively deepening the application, regulating and promoting the service of "Internet plus Health and Medical Treatment", and enhancing the construction of the security system. Specifically, the Opinions clarify that we shall built a unified, authoritative and interconnected population health information platform; advance the sharing and disclosure of resources in the big data on health and medical treatment; and boost the application of big data on the governance, clinical applications and research and development in respect of the health and medical treatment industry, and on the public health.

3. 详情 Details：《关于促进和规范健康医疗大数据应用发展的指导意见》
The Guiding Opinions on Promoting and Regulating the Application and Development of Big Data on Health and Medical Treatment

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（二）食品药品监管总局等四部门关于印发捐赠药品进口管理规定的通知

Circular of Four Departments including the China Food and Drug Administration on Issuing the Administrative Provisions on the Import of Donated Drugs

1. 颁布详情 Enacted details

1) 颁布部门 Promulgated authority: the China Food and Drug Administration
2) 颁布日期 Promulgation date：June8,2016
3) 生效日期 Effective day：October1, 2016

2. 具体内容 Contents

2016年5月20日，为加强捐赠药品进口管理，保证捐赠药品质量安全，食品药品监管总局、民政部、国家卫生计生委、海关总署共同组织制定了《捐赠药品进口管理规定》。内容如下：

适用范围和要求

国外政府、制药企业或相关组织、机构自愿无偿向国内受赠人捐赠药品办理进口备案，适用本规定。

捐赠人应对捐赠药品的质量负责，捐赠时须向受赠人提供药品清单和捐赠药品检验报告。

捐赠药品的条件

捐赠药品必须满足以下条件：
1．捐赠药品应为我国已批准进口注册的品种。
2．捐赠药品有效期限距失效日期须在12个月以上；药品批准有效期为12个月及以下的，捐赠药品有效期限距失效日期须在6个月以上。
3．捐赠药品最小包装的标签上应加注“捐赠药品，不得销售”或类似字样，并附中文说明书。
4．捐赠药品不得上市销售，不得向使用者收取费用。

受赠人的条件和责任

1．捐赠药品的受赠人包括：

1) 国务院有关部门和各省、自治区、直辖市人民政府及其指定的公益性事业单位；
2) 以保护人民生命健康、从事人道主义工作为主要宗旨的全国性人民团体；
3) 在省级以上民政部门依法登记并取得3A以上评估等级、以从事医疗救助、紧急救援、扶贫济困为主要宗旨的慈善组织。

2．受赠人应保证捐赠药品储存、运输、分发等环节符合《药品经营质量管理规范》要求，以保证药品质量。

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3．受赠人应当制定捐赠药品管理的相关制度，严格按规范对捐赠药品登记造册、妥善保管，并详细记录捐赠药品的核销注销情况，确保捐赠药品的可追溯性。捐赠药品质量验收合格的，由受赠人或其委托的代理机构在外包装上加贴“捐赠品已查验”的标识后，方可分发。同时，受赠人应负责捐赠药品的监督使用，承担使用过程中风险的防范和处理职责。如需销毁捐赠药品，应按药品销毁的有关法规和技术要求进行。

4．受赠人应及时将捐赠药品分发使用情况向省级食品药品监管和卫生计生行政管理部门报告，并向所在地省级食品药品监管和卫生计生行政管理部门提交书面报告。

捐赠药品的进口备案程序要求

国家食品药品监督管理总局授权的药品进口口岸所在地食品药品监督管理局负责受理捐赠药品进口的备案申请，办理进口备案的有关事项，通知口岸药品检验所对捐赠药品实施口岸检验，并对捐赠药品进口备案和口岸检验中发现的问题进行监督处理。

捐赠药品进口备案按以下程序办理：

1．受赠人或其委托的代理机构向口岸食品药品监督管理局申请办理《进口药品通关单》时，应同时报送以下资料：

1) 捐赠药品进口备案的书面申请，内容包括捐赠药品的名称、剂型、规格、产地、生产批号、有效期、数量、拟进口口岸等内容，以及对捐赠药品监督使用和风险防范的承诺。
2) 受赠人社会组织登记证或组织机构代码证复印件及资质条件证明。
3) 捐赠协议复印件。
4) 相关药品的《进口药品注册证》（或者《医药产品注册证》）（正本或者副本）复印件。
5) 药品说明书及包装、标签等资料的复印件，外文资料需附相应的中文译本。
6) 原产地证明复印件。
7) 装箱单、提运单和货运发票复印件。
8) 出厂检验报告书复印件。

上述各类复印件应当加盖申请进口单位公章或受赠单位公章。

2．口岸食品药品监督管理局受理上述资料后，按照《药品进口管理办法》规定程序对有关资料进行审查，逐项核查捐赠药品进口申请资料和证明性文件的完整性、真实性。

3．口岸食品药品监督管理局审查全部资料无误后，准予进口备案，发出《进口药品通关单》，同时向负责检验的口岸药品检验所发出《进口药品口岸检验通知书》并附《药品进口管理办法》所规定的有关资料。对于国家食品药品监督管理总局规定的生物制品，须经口岸药品检验所检验符合标准规定后，方可办理进口备案手续。

4．口岸药品检验所应当到《进口药品口岸检验通知书》规定的抽样地点抽取样品，进行质量检验，将检验结果送交所在地口岸食品药品监督管理局并通知送检单位。捐赠药品须经检验合格后方可分发使用。对检验不符合标准规定的捐赠药品，由口岸食品药品监督管理局依照《中华人民共和国药品管理法》及有关规定处理。对于捐赠药品，口岸药品检验机构可优先予以检验。

口岸食品药品监督管理局应于每年12月底前向国家食品药品监督管理总局提交本年度受理的捐赠药品进口情况报告，内容包括捐赠药品的品种、数量、剂型、规格、生产厂名称等信息。

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捐赠药品的监督管理

食品药品监管和卫生计生行政管理部门依职责对捐赠药品的进口备案和分发使用管理情况进行监督检查，海关按《药品进口管理办法》有关要求对其实施监管。

受赠人未按要求建立捐赠药品管理和追溯制度，未按有关规定贮存、运输、分发捐赠药品，或未对污染或变质的捐赠药品按要求销毁的，监管部门将责令其改正，并向社会公告；若发现存在销售捐赠药品或向受赠者收取费用、使用超过有效期的捐赠药品，以及监管部门认定的其他违法违规情形的，监管部门将根据《中华人民共和国公益事业捐赠法》《中华人民共和国药品管理法》有关规定依法查处。

On May 20, 2016,in order to strengthen the administration over the import of donated drugs, ensure the quality and safety of donated drugs, the China Food and Drug Administration, the Ministry of Civil Affairs, the National Health and Family Planning Commission and the General Administration of Customs have jointly formulated the Administrative Provisions on the Import of Donated Drugs.The details as the follow:

I. Scope and Requirements of Application

These Provisions shall apply to the circumstances where the drugs that are voluntarily donated by foreign governments, pharmaceutical enterprises, or relevant organizations and institutions to domestic donees for free are filed for record for the purpose of import.
Donators shall be responsible for the quality of donated drugs and shall provide the donees with the drug lists and corresponding inspection reports for such donated drugs upon the donation.

II. Conditions for Donated Drugs

Donated drugs must meet the following conditions:
1. Donated drugs shall be the varieties for which the State has approved the import registration.
2. The valid period of donated drugs shall be more than 12 months before the expiration date; if the valid term of donated drugs approved is 12 months or below, the valid period of donated drugs shall be more than six months before the expiration date.
3. The smallest packages of donated drugs shall be labelled with such words "Donated Drugs Cannot Be Sold" or similar wording and directions in Chinese shall be attached as well.
4. Donated drugs shall not go on sale nor charge users any fee.

III. Qualifications and Responsibilities of Donees

1. Donees of donated drugs shall include:
(1) Relevant departments under the State Council, people's governments of all provinces, autonomous regions and municipalities directly under the Central Government and their designated public-welfare institutions;
(2) National mass organizations that are aimed at protecting people's lives and health, and engaging in humanitarian work;
(3) Charitable organizations that register at civil affairs departments above the provincial level according to law and achieve an assessment level above 3A, with a main aim of engaging in medical assistance, emergency relief and poverty alleviation.

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2. Donees shall guarantee that the reserve, transportation and distribution of donated drugs and other stages shall meet the requirements of the Good Supply Practice for Pharmaceutical Products to ensure the quality of donated drugs.
3. Donees shall formulate relevant systems concerning the administration of donated drugs, strictly follow the Practice as mentioned above to keep a register of the donated drugs for safekeeping. They shall also keep detailed records of the verification and deregistration conditions of donated drugs to ensure the traceability thereof. Qualified donated drugs may be distributed after donees or agencies they entrust have attached a label with words "Donation Inspected" on the exterior package. Meanwhile, donees shall be responsible for supervising the use of donated drugs and bear the duties of risks prevention and treatment in the process of use. Where donated drugs need to be destroyed, it shall be conducted according to relevant laws and technical requirements on drug destruction.
4. Donees shall inform the provincial food and drug administrations and the family planning administrative departments of the distribution and use of donated drugs in time and submit the written report to the provincial food and drug administrations and the family planning administrative departments at the places where they are located.

IV. Import Record-filing Procedural Requirements for Donated Drugs

The local food and drug administration bureaus at ports of imported drugs authorized by the China Food and Drug Administration are responsible for accepting the application for the import record-filing of donated drugs, handling related matters of import record-filing, informing the port drug inspection institutions to conduct port inspection of donated drugs, and supervising and dealing with problems resulted from the import record-filing and port inspection of donated drugs.
Import record-filing of donated drugs shall be handled according to the following procedures:
1. When donees or the agencies they entrust apply to the food and drug administration bureaus at ports for Drug Import Customs Clearance Permit, they shall submit the following materials at the same time:
(1) A written application for filing a record for the import of donated drugs, including the names, dosage forms, specifications, places of origin, production lot number, expiration date, quantity, the ports through which such drugs will be imported and other information, as well as the promise to supervise the use of donated drugs and prevent risks concerned.
(2) Copies of the donees' Registration Certificate of Social Organizations or Organization Code Certificate and qualification proof.
(3) Copies of donation agreements.
(4) Copies of the Imported Drugs Registration Certificate (or Pharmaceutical Products Registration Certificate) (the original copy or the duplicate copy) for relevant drugs.
(5) Copies of pharmaceutical directions, packages and labels of imported drugs, while corresponding Chinese translations shall be attached to materials in foreign languages.
(6) Copies of certificates of origin.
(7) Copies of packing lists, bills of freight and shipping invoices.
(8) Copies of factory inspection reports.
All the copies mentioned above shall be stamped with the official seal by the entities which apply for the import or the entities which receive the donated drugs.
2. Food and drug administration bureaus at ports shall examine related materials according to the Administrative Measures for the Importation of Drugs after accepting the above materials and inspect the integrity and authenticity of application materials and credentials related to the import of donated drugs term by term.
3. Food and drug administration bureaus at ports shall approve the import record-filing and issue the Drug

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Import Customs Clearance Permit provided that no mistake is found in the examination of above-mentioned materials and, meanwhile, release the Imported Drugs Port Inspection Notice to the corresponding port drug inspection institutions and append the relevant materials required in the Administrative Measures for the Importation of Drugs. For biological products defined by the China Food and Drug Administration, they shall be filed for record for the purpose of import after being examined by port drug inspection institutions and proved to be up to the certain standards.

4. Port drug inspection institutions shall go to certain sample locations defined in the Imported Drugs Port Inspection Notice to draw samples and carry out quality inspection, and submit the inspection results to the food and drug administration bureaus at the local ports and inform the inspection application institutions of the same. Donated drugs shall be distributed and used after being proved qualified by inspections. For donated drugs that do not meet certain standards, the food and drug administration bureaus at all ports shall dispose them according to the Drug Administration Law of the People's Republic of China and relevant provisions. Port drug inspection institutions may inspect donated drugs with priority.

The food and drug administration bureaus at all ports shall submit reports for the accepted import applications of donated drugs in the current year to the China Food and Drug Administration by the end of December every year, including the varieties, quantities, dosage forms, specifications, names of manufacturers of donated drugs and other information.

V. Supervision and Administration of Donated Drugs

The food and drug administrations and the family planning administrative departments shall supervise and examine the administration over the import record-filing and distribution and use of donated drugs, while the customs shall conduct supervision according to the related requirements as stipulated in the Administrative Measures for the Importation of Drugs.

Where donees fail to establish an administration and traceability system of donated drugs as required, fail to reserve, transport and distribute donated drugs according to related provisions, or fail to destroy polluted or spoiled donated drugs as required, the supervisory departments shall order them to make rectifications and announce the same to the public; in cases of selling donated drugs, charging donees, using expired donated drugs or other illegal situations identified by the supervisory departments, the supervisory departments shall investigate and deal with them according to the relevant provisions of the Law of the People's Republic of China on Donations for Public Welfare and the Drug Administration Law of the People's Republic of China.

3. 详情 **Details：** 食品药品监管总局等四部门关于印发捐赠药品进口管理规定的通知

Circular of Four Departments including the China Food and Drug Administration on Issuing the Administrative Provisions on the Import of Donated Drugs

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（三）《关于贯彻实施新修订〈疫苗流通和预防接种管理条例〉的通知》
Circular on Implementing the Revised Administrative Regulations on the Circulation of Vaccines and Vaccination

1. 颁布详情 Enacted details

1) 颁布部门 Promulgated authority:The China Food and Drug Administration
2) 发布日期 Promulgation date: June14,2016
3) 生效日期 Effective date: June14,2016

2. 跟踪报道 Related content

为贯彻落实《疫苗流通和预防接种管理条例》，规范我国疫苗流通和预防接种管理，国家食品药品监管总局、国家卫生计生委发布《关于贯彻实施新修订〈疫苗流通和预防接种管理条例〉的通知》（《通知》）。

《通知》称，原疫苗经营企业在 2016 年 4 月 25 日前已购进的第二类疫苗可继续销售至各级疾病预防控制机构，由其进行供应。原疫苗经营企业 2017 年 1 月 1 日起必须停止疫苗销售活动，向原发证的食品药品监督管理部门申请注销《药品经营许可证》或核减疫苗经营范围。各级疾病预防控制机构在 2016 年 4 月 25 日前已购进的第二类疫苗，在 2016 年 12 月 31 日前，可按照逐级供应方式供应。《通知》同时加强了配送要求及追溯体系。要求疫苗生产企业直接向县级疾病预防控制机构配送第二类疫苗，或委托具备冷链储存、运输条件的企业配送时，应当严格遵守药品 GSP 相关要求。

In order to thoroughly carry out the Administrative Regulations on the Circulation of Vaccines and Vaccination and regulate the circulation of vaccines and vaccination, the China Food and Drug Administration and the National Health and Family Planning Commission have issued the Circular on Implementing the Revised Administrative Regulations on the Circulation of Vaccines and Vaccination (the "Circular").

According to the Circular, original vaccine distributors may continue to sell the vaccines of Class 2 purchased before April 25, 2016 to institutions of disease prevention and control at various levels for vaccine supply. Original vaccine distributors must cease all vaccine sales from January 1, 2017, and apply to the original food and drug administrative departments that issued Drug Distribution Certificates to them for cancellation of such certificates or approval of smaller scope of vaccine distribution. Institutions of disease prevention and control at various levels may supply the vaccines of Class 2 purchased before April 25, 2016 level by level prior to December 31, 2016.The Circular also stresses that the requirements on the distribution and traceability system shall be fulfilled. Where vaccine producers distribute the vaccines of Class 2 to the institutions of disease prevention and control at the county level by themselves or by entrusting the enterprises with conditions for cold chain storage and transport, all the parties involved shall strictly comply with the relevant GSP requirements for pharmaceutical products.

3. 详情 Details： 《关于贯彻实施新修订〈疫苗流通和预防接种管理条例〉的通知》
Circular on Implementing the Revised Administrative Regulations on the Circulation of Vaccines and Vaccination

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（四）《婴幼儿配方乳粉产品配方注册管理办法》

Administrative Measures for Registration of Formulas of Infant Formula Milk Powder Promulgated

1. 颁布详情 Enacted details

1) 颁布部门 Promulgated authority: the China Food and Drug Administration
2) 颁布日期 Promulgation date：June8,2016
3) 生效日期 Effective day：October1, 2016

2. 跟踪报道 Related content

2016 年 6 月 8 号，国家食药监总局发布《婴幼儿配方乳粉产品配方注册管理办法》（《办法》），《办法》共 6 章 49 条，将于 2016 年 10 月 1 日起施行。

《办法》要求，设立注册门槛，提高生产要求。参照药品管理，明确我国境内生产销售和进口的婴幼儿配方乳粉产品配方均实行注册管理，并严格限定申请人资质条件。

《办法》明确，限制配方数量，要求每个企业原则上不得超过 3 个配方系列 9 种产品配方，同时《办法》允许同一集团公司全资子公司可使用集团公司内另一全资子公司已经注册的产品配方。《办法》还要求申请人申请注册时一并提交标签和说明书样稿及标签、说明书中声称的说明、证明材料，并对标签和说明书表述要求作出细致规定。

On June 8,2016,the China Food and Drug Administration has recently promulgated the Administrative Measures for the Registration of Formulas of Infant Formula Milk Powder (the "Measures") which consist of 49 articles in six chapters, with effect as of October 1, 2016.

The Measures require the setting of the threshold for registration and improvement of production requirements. By reference to drug administration, the Measures specify that formulas of infant formula milk powder produced and sold within the territory of and imported to China are subject to the registration administration, and strictly define an applicant's qualifications.

The Measures set out the limit on the number of formulas by stipulating that each enterprise shall, in principle, have no more than nine product formulas under three formula series, and allow a wholly-owned subsidiary under a group company to use the formulas registered by another wholly-owned subsidiary under the same group company. In addition, the Measures require applicants to submit sample labels and instructions as well as descriptions and supporting materials for the claims set forth therein when they apply for registration, and set out detailed provisions on the requirements for statement of such labels and instructions.

3. 详情 Details：《婴幼儿配方乳粉产品配方注册管理办法》全文

Administrative Measures for Registration of Formulas of Infant Formula Milk Powder Promulgated

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二、医药行业最新监管动态

The latest regulatory developments in the pharmaceutical industry

（一）内资&外资医院设立程序[1]

Procedures on Domestic & foreign hospitals established

◆ 内资设立民办医院的条件

县级以上地方卫生行政部门会依据1994年9月5日卫生部发布的 《医疗机构设置规划指导原则》，根据本行政区域内的人口、医疗资源、医疗需求和现有医疗机构的分布状况，制定出《医疗机构设置规划》，在经上一级卫生行政部门审核并报同级人民政府批准后，在本行政区域内发布实施。而设立民办医院应当符合该地区的《医疗机构设置规划》和1994年卫生部所发布的《医疗机构基本标准》。

1. 设立的内资医疗机构应当符合以下基本条件：

1) 设置医疗机构的批准书；
2) 符合医疗机构的基本标准；
3) 有适合的名称、组织机构和场所；
4) 有与其开展的业务相适应的经费、设施、设备和专业卫生技术人员；
5) 有相应的规章制度；
6) 能够独立承担民事责任。

2. 禁止性条件

同时《医疗机构管理条例实施细则》特别强调有下列情形之一的，不得申请设置医疗机构，包括民办医院：

1) 不能独立承担民事责任的单位；
2) 正在服刑或者不具有完全民事行为能力的个人；
3) 医疗机构在职、因病退职或者停薪留职的医务人员；
4) 发生二级以上医疗事故未满五年的医务人员；
5) 因违反有关法律、法规和规章，已被吊销执业证书的医务人员；
6) 被吊销《医疗机构执业许可证》的医疗机构法定代表人或者主要负责人；
7) 省、自治区、直辖市政府卫生行政部门规定的其他情形。

其中，有第2）、3）、4）、5）、6）项所列情形之一者，不得充任民办医院的法定代表人或者主要负责人。

◆ 外资设立民办医院的条件

1. 设立的中外合资、合作医疗机构应当符合以下基本条件：

1) 必须是独立的法人；

[1] 本文由北京大成（上海）律师事务所 沈涛律师整理

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2) 投资总额不得低于2000万人民币；
3) 合资、合作中方在中外合资、合作医疗机构中所占的股权比例或权益不得低于30%；
4) 合资、合作期限不超过20年；
5) 省级以上卫生行政部门规定的其它条件。

2. 其他条件

中外合资、合作医疗机构的设置与发展必须符合当地区域卫生规划和医疗机构设置规划，并执行卫生部制定的《医疗机构基本标准》。

申请设立中外合资、合作医疗机构的中外双方应是能够独立承担民事责任的法人。合资、合作的中外双方应当具有直接或间接从事医疗卫生投资与管理的经验，

并符合下列要求之一：

1) 能够提供国际先进的医疗机构管理经验、管理模式和服务模式；
2) 能够提供具有国际领先水平的医学技术和设备；
3) 可以补充或改善当地在医疗服务能力、医疗技术、资金和医疗设施方面的不足。

此外合资、合作中方以国有资产参与投资（包括作价出资或作为合作条件），应当经相应主管部门批准，并按国有资产评估管理有关规定，

由国有资产管理部门确认的评估机构对拟投入国有资产进行评估。经省级以上国有资产管理部门确认的评估结果，可以作为拟投入的国有资产的作价依据。

◆ 内资设立民办医院的程序

开办一家民办医院要经过申请、审批、备案等一系列手续，而且不同规模的医院在设立程序的具体操作上也略有不同：

1. 申请

1) 申请人的要求：法人或者其他组织设置民办医院的，由其代表人申请；个人设置民办医院的，由设置人申请；两人以上合伙设置的，由合伙人共同申请。
2) 受理设立民办医院申请的机关
   ① 不设床位或者床位不满100张的医院，向所在地的县级人民政府卫生行政部门申请；
   ② 床位在100张以上的医院和专科医院按照省级人民政府卫生行政部门的规定申请。
3) 申请设置医疗机构，应当提交的文件：
   ① 设置申请书：
   ② 设置可行性研究报告，具体应包括申请单位名称、基本情况以及申请人姓名、年龄、专业履历、身份证号码；

所在地区的人口、经济和社会发展等概况；所在地区人群健康状况和疾病流行以及有关疾病患病率；所在地区医疗资源分布情况以及医疗服务需求分析；

拟设医疗机构的名称、选址、功能、任务、服务半径； 拟设医疗机构的服务方式、时间、诊疗科目和床位编制；拟设医疗机构的组织结构、人员配备；

拟设医疗机构的仪器、设备配备；拟设医疗机构与服务半径区域内其他医疗机构的关系和影响； 拟设医疗机构的污水、污物、粪便处理方案；

拟设医疗机构的通讯、供电、上下水道、消防设施情况；资金来源、投资方式、投资总额、注册资金（资本）；拟设医疗机构的投资预算；

拟设医疗机构五年内的成本效益预测分析。同时附上申请设计单位或者设置人的资信证明。

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③ 选址报告和建筑设计平面图，其中选址报告应包括选址的依据；选址所在地区的环境和公用设施情况；选址与周围托幼机构、中小学校、
食品生产经营单位布局的关系； 占地和建筑面积。
④ 由两个以上法人或者其他组织共同申请设置医疗机构以及两人以上合伙申请设置民办医院的，还必须提交由各方共同签署的协议书。

2. 审批

审批是设立民办医院的必须程序，只有经县级以上地方人民政府卫生行政部门审查批准，并取得设置医疗机构批准书，才可向有关部门办理其他手续。

1) 审批机关

床位在一百张以上的医院设置审批权限的划分，由省、自治区、直辖市卫生行政部门规定；其他医疗机构的设置，由县级卫生行政部门负责审批。

2) 审批期限

县级以上地方人民政府卫生行政部门应当自受理设置申请之日起30日内，作出批准或者不批准的书面答复；批准设置的，发给设置医疗机构批准书。设置申请的受理时间，自申请人提供条例和本细则规定的全部材料之日算起。

3) 审批机关应当依据当地《医疗机构设置规划》及《医疗机构管理条例实施细则》审查和批准民办医院的设立置。申请设立民办医院有下列情形之一的，不予批准：

① 不符合当地《医疗机构设置规划》；
② 设置人不符合规定的条件；
③ 不能提供满足投资总额的资信证明；
④ 投资总额不能满足各项预算开支；
⑤ 医疗机构选址不合理；
⑥ 污水、污物、粪便处理方案不合理；
⑦ 省、自治区、直辖市卫生行政部门规定的其他情形。

3. 备案

如果申请人的条件符合法定条件，审批机关将向其核发《设置医疗机构批准书》。在核发批准书的同时，审批机关应向上一级卫生行政部门备案。上级卫生行政部门在接到备案报告之日起三十日内，有权纠正或者撤销下级卫生行政部门作出的不符合当地《医疗机构设置规划》的设置审批。

应当注意的是，如果申请人意图变更《设置医疗机构批准书》中核准的医疗机构的类别、规模、选址和诊疗科目，则必须按照《医疗机构管理条例》和《医疗机构管理条例实施细则》的规定，重新申请办理设置审批手续。

◆ 外资设立民办医院的程序

1. 申请程序

设置中外合资、合作医疗机构，应先向所在地设区的市级卫生行政部门提出申请，并提交以下材料：

1) 设置医疗机构申请书；
2) 合资、合作双方法人代表签署的项目建议书及中外合资、合作医疗机构设置可行性研究报告；
3) 合资、合作双方各自的注册登记证明（复印件）、法定代表人身份证明（复印件）和银行资信证明；

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4) 国有资产管理部门对拟投入国有资产的评估报告确认文件。

2. 初审程序

设区的市级卫生行政部门对申请人提交的材料进行初审，并根据区域卫生规划和医疗机构设置规划提出初审意见，并与申请材料、当地区域卫生规划和医疗机构设置规划一起报所在地省级卫生行政部门审核。

报请审批，需由省级卫生行政部门向卫生部提交以下材料：

1) 申请人设置申请材料；

2) 设置地设区的市级人民政府批准发布实施的《医疗机构设置规划》及设置地设区的市级和省级卫生行政部门关于拟设置中外合资、合作医疗机构是否符合当地区域卫生规划和医疗机构设置规划的审核意见；

3) 省级卫生行政管理部门关于设置该中外合资、合作医疗机构的审核意见，其中包括对拟设置中外合资、合作医疗机构的名称、选址、规模（床位、牙椅）、诊疗科目和经营期限等的意见；

4) 法律、法规和卫生部规定的其它材料。

省级卫生行政部门对申请材料及设区的市级卫生行政部门初审意见进行审核后报卫生部审批。

3. 卫生部终审程序

卫生部应当自受理之日起45个工作日内，作出批准或者不批准的书面决定。

4. 其他部委后期审批程序

申请人在获得卫生部设置许可后，按照有关法律、法规向商务部提出申请，并提交以下材料：

1) 设置申请申报材料及批准文件；

2) 由中外合资、合作各方的法定代表人或其授权的代表签署的中外合资、合作医疗机构的合同、章程；

3) 拟设立中外合资、合作医疗机构董事会成员名单及合资、合作各方董事委派书；

4) 工商行政管理部门出具的机构名称预先核准通知书；

5) 法律、法规和外经贸部规定的其它材料。

商务部应当自受理申请之日起45个工作日内，作出批准或者不批准的书面决定；予以批准的，发给《外商投资企业批准证书》。 获得批准设立的中外合资、合作医疗机构，应自收到商务部颁发的《外商投资企业批准证书》之日起一个月内，凭此证书到国家工商行政管理部门办理注册登记手续。

获准设立的中外合资、合作医疗机构，应当按《医疗机构管理条例》和《医疗机构管理条例实施细则》关于医疗机构执业登记所规定的程序和要求，向所在地省级卫生行政部门规定的卫生行政部门申请执业登记，领取《医疗机构执业许可证》。

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三、专业文章
Professional Articles

中国如何保护个人健康信息[2]

与美国通过零散的各部门法对个人信息实施保护的方法类似，中国尚未形成有关个人信息的使用、披露、转移和安全保护的统一立法，个人健康信息的规范立法更是无从谈起。我们也尚未在中国法下看到统一的“个人健康信息”的定义。

此外，中国尚未设立监管隐私保护并执行相关措施的跨部门政府机构。目前，国家卫生和计划生育委员会（“卫计委”）、国家食品药品监督管理总局（“食药监局”）以及科技部根据其不同的职责各自承担着不同的监管和执行医疗健康领域隐私保护措施的职责。以一种不太全面的方式简单来说，卫计委主要负责医疗机构、医疗组织或行政部门方面的健康数据管理，食药监局负责医疗健康产品方面的数据管理，而科技部主要负责人类遗传资源方面的数据管理。

本文将简述中国法项下有关个人健康数据保护的基本法律框架，梳理中国法律对于在中国采集和使用“个人健康数据”的监管要求。

禁止利用网络公开个人健康数据

一般来说，基因信息、病历记录和健康检查材料属于健康数据的范畴。除某些豁免的情形外，中国法律明确禁止利用网络公开此类数据（《最高人民法院关于审理利用信息网络侵害人身权益民事纠纷案件适用法律若干问题的规定》（法释[2014]11 号），2014 年10 月10 日起生效）。

人口健康信息

2014 年，卫计委颁发《人口健康信息管理办法（试行）》（“办法”）。该办法中首次出现了“人口健康信息”的概念，并对此进行了定义：人口健康信息，是指各级各类医疗卫生计生服务机构在服务和管理过程中产生的人口基本信息、医疗卫生服务信息等人口健康信息。卫计委在《办法》的解读中进一步明确，人口健康信息主要包括全员人口信息、计划生育信息、电子健康档案、电子病历以及人口健康统计信息等。根据《电子病历基本架构与数据标准（试行）》，健康检查、检查检验记录或门（急）诊处方均构成病历的一部分，应属于人口健康信息。《办法》禁止将人口健康信息存储在境外服务器上。

通读《办法》之后，对于客户提出的一些问题，我们仍然未能找到明确答案，例如：什么情况下可以合法地传输健康数据？匿名的健康数据是否仍受《办法》管辖，从而被禁止向境外接收者传输？临床试验中产生的匿名但重新编号的健康数据（该编号不会向赞助方披露，编号与真实姓名的比对表掌握在医疗机构手中）是否可以为研究或记录目的而向境外赞助方（例如药品或医疗器械企业）传输？

健康数据跨国流动

2011 年，国家质量监督检验检疫总局及国家标准化管理委员会联合发布的《健康信息学 推动个人健康信息跨国流动的数据保护指南》正式实施，该《指南》规定了个人健康数据跨国运输的数据保护要求。除保护数据主体切身利益所必要的传输之外并且数据导入方能够提供充分的数据保护，个人健康数

[2] 本文由北京大成（上海）律师事务所王忻、汪丞竹律师撰写

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据不应传输，除非得到数据主体明确的同意。此外，跨国传输个人健康数据的解决方案可以是将数据非个人化，使得保留明显的可标识信息，并确保数据导入方不重新标识个体或不透露超出所同意使用目的要求的匿名信息，这意味着匿名处理的信息即可向境外传输。但是，该《指南》为推荐性国家标准(GB/T)，并非强制性，因此除非在协议中明确约定接受该指南的管辖，否则不具备法律上的约束力。此外，该《指南》的制定参考了欧盟的《关于涉及个人数据处理的个人保护以及此类数据自由流动的指令》，随着《指令》的即将失效及最新通过的《一般数据保护条例》的诞生，该指南很有可能于近期发生更新。同时，由于《办法》规定了禁止将人口健康信息存储在境外服务器上，我们认为基于遵守《办法》的目的，人口健康信息数据不能物理传输到境外或在境外服务器上进行处理，从这个意义上讲，除非进行大幅度的更新，此《指南》的现实指导意义可能已经不大。

医院方面的健康信息保护

关于医院日常运行中对个人隐私保护方面，原卫生部颁布的《电子病历系统功能规范（试行）》对医院使用的电子病历系统提出了要求。患者隐私保护功能是电子病历系统必须具备的功能之一，尤其应当对访问权限实行分级管理。系统授权保密等级较低者无权访问保密等级较高的病历记录。此外，当医务人员需要查看非直接相关患者的电子病历资料时，电脑屏幕上必须显示注意事项，提醒使用者要依照规定使用患者电子病历资料。提供对电子病历进行患者匿名化处理也是强烈推荐的功能之一。

人类基因数据

人类基因数据是人类遗传资源的一部分。人类遗传资源指含有人体基因组、基因及其产物的器官、组织、细胞、血液、制备物、DNA 构建体等遗传材料及相关的信息资料。以下有关人类基因数据的活动应当根据《人类遗传资源管理暂行办法（1998）》以及《人类遗传资源采集、收集、买卖、出口、出境审批行政许可事项服务指南（2015）》的规定，由科技部批准之后方能实施：

(a) 将人类遗传资源传输至境外；
(b) 与外方或外商投资企业合作采集人类遗传资源；
(c) 采集特定区域或重要遗传家系的遗传资源（无论是否涉及外方参与）。

《人类遗传资源管理条例（送审稿）》已于2016 年2 月公开征求意见。该送审稿下，任何单位或个人买卖人类遗传资源都是禁止的。目前为止，上述需要科技部前置审批的事项大多适用于与人类遗传资源相关的涉及外方参与的临床试验项目或中外合作项目。

伦理审查

根据《涉及人的生物医学研究伦理审查办法(试行)（2007）》，涉及人的生物医学研究，包括对人的生理、病理现象以及疾病的诊断、治疗和预防方法进行研究的活动以及通过医疗卫生技术或者产品在人体上进行试验性应用的活动，均属于伦理审查的范围。伦理审查的重要原则之一是尊重和保护受试者的隐私，包括告知受试者其个人数据的使用情况及保密措施、不得向无关的第三者或者传播媒体透露等。卫计委于2014 年公布了修改后的《涉及人的生物医学研究伦理审查办法(征求意见稿)》并公开征求意见。若最终得以生效，该征求意见稿将进一步要求，受试者的知情同意书应当包括研究数据和受试者个人资料的保密，并且研究人员应当告知受试者有其身份标识的记录的保密范围和办法。

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人口健康大数据

国务院办公厅于2016 年6 月21 日发布了《关于促进和规范健康医疗大数据应用发展的指导意见》，旨在为了实现2017 年底跨部门健康医疗数据资源共享格局及2020 年建立国家医疗卫生信息分级开放应用平台，应加快制定健康医疗大数据的开放和保障机制。国家卫生计生委副主任此前表示，健康医疗大数据是涵盖人的全生命周期，既包括个人健康，又涉及医药服务、疾病防控、健康保障和食品安全、养保健等多方面数据的汇聚和聚合。该《指导意见》对于国家、各省市制定保障健康医疗数据资源权益和网络数据安全有关法规政策有促进和指导的重大意义。

How China Protects Personal Data Concerning Health

Similar with the sectoral approach to personal data taken by the United States, China lacks anomnibus framework regulating the use, disclose, transfer and security of personal data, not to speak of those concerning health. We never see a unified definition on personal data concerning health under PRC law.
In the meanwhile, there is no cross-sector government body established taking the supervisory role to oversee and enforce the privacy protection. National Health and Family Planning Commission (NHFPC), China Food and Drug Administration (CFDA) and Ministry of Science and Technology (MOST) take respective responsibilities to oversee and enforce the privacy protection in the healthcare industry in China. To put it simple, NHFPC focuses on data issues with respect to medical institutions, organizations or administrations, so does CFDA withrespect to health care products and MOST on human genetic resources.

No Publication through Internet

In general, it is understood that genetic information, medical record and health examination materials should fall within the scope of health data. Such data is clearly protected from publication through internet except for those exempted circumstances (Provisions of the Supreme People’s Court on Application of Laws to Cases Involving Civil Disputes over Infringement upon Personal Rights and Interests by Using Information Networks (No. 11 [2014]) (effective on 10 Oct 2014).

Population Health Information

In 2014, NHFPC issued Measures for the Management of Population Health Information (for Trial Implementation) (“Measures”). A concept of “population health information” was created and defined including basic population information, medical service information and other population health information generated by medical, health and family planning service agencies at all levels in performing their services or in the course of administration. NHFPC further clarifies, in an interpretation document, that population health information includes e.g. household registration information, birth control information, electronic health records (EHR), electronic medical reports (EMR) and population health statistics etc. According to Basic Structure and Data Standard of EMR (for Trial Implementation), medical examination, laboratory test record or prescription should constitute part of EMR and therefore be categorized as population health information. According to the Measures, population health data is prohibited from storing on offshore servers.

Having read through the Measures, we did not locate clear answers to certain questions raised by our healthcare clients such as: on what conditions a legitimate health data transfer can take place? whether anonymized health data should be subject to the Measures and therefore be prohibited from transferring to offshore recipients? whether anonymized but key-coded, i.e. pseudonymization, health data generated in the

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course of clinical trial (the key will not be revealed to the sponsors) can be transferred to offshore sponsors (i.e.pharmaceutical or medical device companies) for research or registration purposes?

Trans-border Health Data Flow

In 2011, Health Informatics - Guidelines on Data Protection to Facilitate Trans-border Flows of Personal Health Information (“Guidelines”) jointly released by General Administration of Quality Supervision, Inspection and Quarantine and Standardization Administration took effect, which regulates the requirements of the protection of population health information on the cross-border transfer. Unless the transfer of the data is necessary for the purpose of protecting the vital interest of the data subject and the dataimporter have provided sufficient data protection, the health information shall not be transmitted, except that express consent of the data subject is obtained. In addition, to realize trans-border personal health data flow, the data exporter may process the data into anonymized information, by deleting the obvious identifiable information with replacement by artificial identifiers and forbidding the data importer from re-marking any subject or disclosing the anonymized data to any person unless for the agreed purpose of use. By taking such a safety measure, anonymized health data can be transferred to offshore recipient. However, the nature of the Guidelines is a recommended, not compulsory, national standard (GB/T), thus it has no legal binding force unless incorporating the Guidelines into the agreement. Furthermore, the Guidelines is made inaccordance with Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (“Directive”), as with the to-be-invalid Directive and the issuance of the new legislation - General Data Protection Rule (“GDPR”), the Guidelines may be updated in the near future. In the meanwhile, the Measures mentioned above request that population health data is prohibited from storing on offshore servers which appears being in conflict with the Guidelines, thus we think that,in this sense, the Guidelines might need to be updated as soon as possible.

Health Data Protection in Hospitals

In terms of privacy protection in hospital’s daily operation, the Ministry of Health (the former name for NHFPC) issued the Standards for the Function of Electronic Medical Record System which sets out the requirements for the electronic medical record system operated in the hospitals. The privacy protection function is a must in such a system.Particularly, there must exist different levels of authorization for accessing to the information. System users who only have lower level of authorization are not entitled to read the records which require higher level of authorization. In addition, if a doctor wants to read the medical records of a non-related patient, a notice must appear on the screen to remind the doctor of properly using the records. Anonymization of patient’s data is also highly recommended as one function.

Human Genetic Data

Human genetic data is part of human genetic resources which refer to those genetic materials (e.g. organ, tissue, cell, blood, fraction, DNA constructs) containing human genome, gene or their related products as well as relevant data arising therefrom. The following activities in relation to human genetic data should be subject to pre-approval by MOST in accordance with *Provisional Administrative Measures on Human Genetic Resources (1998) and Service Guidance on Approving Collection, Gathering, Trading,Exporting and Exit of Human Genetic Resources (2015):*

(a) transmitting such data to offshore;
(b) collecting such data in cooperation with a foreign party or a foreign invested enterprise; or
(c) collecting such data with respect to specific regions1 or important genetic families2(irrespective of any

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foreign element involved or not).

Administrative Measures on Human Genetic Resources (Exposure Draft) was issued in February 2016 for soliciting public comments. Under this draft, selling human genetic resources (including data) is expressly prohibited.
So far, the above MOST pre-approval mostly applies to clinical trial with foreign involvement and Sino-foreign cooperation project pertaining to human genetic resources.

Ethical Review

In accordance with Ethical Review Measures on Human Biomedical Research (Trial Implementation) (2007), biomedical research on human, which includes those research activities on diagnostics, treatment and preventive measures for physiology, pathology or disease of human and clinical trial for drugs or medical devices/technologies, should be subject to ethical review. One important principal for ethical review is protecting the subject's privacy e.g. to check if there is a prior-notification to the subject on the data use and confidentiality measures, prohibition from disclosing to any irrelevant party or media.

A modified Ethical Review Measures on Human Biomedical Research (Draft for Comments) issued in 2014 (if taking effect eventually) further requests that the consent form by the subject should include the confidentiality on research data and privacy protection, and the researcher should inform the subject of the scope and measures of the confidentiality in relation to any record containing the subject's identification.

Population Health Big Data

On 21 June 2016, Guiding Opinions on Improving and Regulating the Implication and Development of Healthcare Big Data ("Guiding Opinions") was issued by the General Office of the State Council, which provides that for the purpose of realizing cross-sector health care data resource sharing mechanism by the end of 2017 and establishing a levelbased open-mode application platform for national medical and health information, by 2020, the sharing and security mechanism for the healthcare big data shall be promulgated.A senior official of NHFPC defined the healthcare big data, in his previous speech, as a convergence and gathering of many kinds of data such as personal health data, and data with respect to medical service, disease control and prevention, health protection and food safety, and health preservation which should cover the whole life cycle of a human being.The Guiding Opinions has significant influence on promoting and guiding all levels of government to enact the rules to safeguard the healthcare data resource rights and interests and network data security.

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四、大成医药卫生法律服务团队法律简报

Legal News on Health care legal service team

研讨会：互联网+医疗行业发展态势及法律风险控制

Seminar： Internet + medical industry development trend and Legal Risk Control

2016年6月17日下午，由北京大成（上海）律师事务所沈涛、何春锋律师主办了 “互联网+医疗行业发展态势及法律风险控制研讨会”。来自平安保险、太平保险、君康人寿、美亚保险、正大天晴药业、药明生物、绿谷制药、新华医院、上海市第五人民医院、美高投资等公司和机构相关人员出席研讨会，并围绕“互联网+医疗”进行了深入探讨。

会议开始前，两位律师先与每位来宾进行了互相介绍。会议主要围绕“互联网+医疗行业发展态势、我国三大互联网巨头BAT的医药布局、互联网+医疗行业的主要发展领域及商业模式”进行了论述，并对未来几年“互联网+医疗行业发展潜力方向”进行了简要分析。两位律师一起探讨了“互联网+医疗行业主题法律关系”，详细介绍了互联网+医疗行业的相关法律法规，接下来分别从互联网平台企业、医疗机构、医生、患者角度，具体讲述了“互联网+医疗行业的法律风险控制”。最后，现场互动环节，两位律师和现场来宾进行了深入、有效的沟通。

✓ **Please feel free to contact us if you have any further request.**
有任何进一步疑问敬请随时和我们团队联系。

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