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Compliance Tips for Medical Health APPs (Part I) - Regulatory Requirements regarding Medical Devices and Advertising

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Series Foreword

The Internet has been changing our lives at an unprecedented pace. In addition to E-shopping and food delivery, Internet medical services have become a significant part of our life. People start trying online diagnosis services when they feel sick; when they visit a doctor, they make online appointments beforehand; people also buy pharmaceuticals online as opposed to from brick and mortar pharmacies. Moreover, Internet medical services have permeated into our life, largely unnoticed. Our watches can measure our heart rate, electrocardiograph and even blood pressure, and more and more medical tests and assessments that were only available at hospitals can now be done remotely from home.

In tandem with growth opportunities, the fast-developing Internet medical technologies also pose new compliance challenges to business operators. What is the scope of legitimate online drug sales? Can prescription drugs be sold online? What telecommunication permits and approvals are required for online diagnosis, registration and sales via an APP? Do APPs and devices that feature medical monitoring or testing constitute medical devices? What are the requirements on drug transportation and logistics? How to protect personal information in Internet medical services? These are all common questions related to Internet medical services, yet their answers are far from clear to those who run the businesses.

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Based on our law practices, we have prepared a series of articles in relation to Internet medical services, in the hope to help healthcare businesses to better understand relevant legal framework and regulatory trends. **This article is the second of the series: Compliance Tips for Medical Health APPs (Part I) - Regulatory Requirements regarding Medical Devices and Advertising.**

With the rapid development of big data, cloud computing, Internet of Things, artificial intelligence and other technologies, the Internet medical market has been booming, and "Internet + Medical Health" has become an investment hotspot among public medical institutions and pharmaceutical companies. The data from Qianzhan Industry Research Institute shows that the scale of China's Internet medical market is expected to reach RMB 90 billion in 2020. As an important branch of Internet medical industry, mobile health plays a significant role in improving patient experience, reallocating medical resources, and enhancing health management.

Mobile health refers to the healthcare services supported by mobile internet technology and provided by various mobile internet platforms. Among various forms of mobile health services, medical health Apps are most typical. The functions of such Apps have basically covered the entire medical treatment process from pre-diagnosis to post-diagnosis, including online inquiry, pre-diagnosis consultation, online registration, online payment, online query of test results, health education and management, doctor-patient communication, post-diagnosis follow-up, data collection, chronic disease management, remote monitoring, Internet drug sales, doctors or patients communities. As the functions, requirements, and business models of medical health Apps are becoming increasingly diverse, the channels and types of data collected by Apps, and the purpose and methods of collecting and processing have become more complicated. Combining laws and regulations with our law practice experience, the authors will analyze the compliance tips for medical health Apps in this article. Part I contains analysis on compliance tips for the advertising activities related to medical health Apps based on the attributes of medical health Apps, and Part II focuses on the personal information collection and use of medical health Apps.

Part I

I. Whether a medical health App constitutes medical device

1. Definition of mobile medical device

In 2003, the former China Food and Drug Administration (CFDA) included medical device software in the medical device regulatory directory. In the context of the continuous empowerment of network technology in the medical industry, the CFDA issued the *Guiding Principles for the Technical Review on Mobile Medical Device Registration* (hereinafter referred to as the "*Guiding Principles*") in 2017, which includes non-invasive "Mobile Computing Terminals" (including general-purpose terminals and special-purpose terminals) software for medical purposes in the scope of mobile medical devices. According to the *Guiding Principles*, software used in handheld, wearable, and hybrid formats may be considered as medical devices. Medical health App is a third-party application software program that provides users with medical health services through handheld terminals, such as portable computers, tablet computers, and smart phones. The National Medical Products Administration (NMPA) issued the *Appendix to Quality Management Specifications for Medical Device Production - Independent*

Software (hereinafter referred to as the "*Independent Software Appendix*") in July 2019, further strengthening the special supervision of independent software medical devices. App identified as a medical device should abide by relevant laws and regulations on medical device management.

According to different classification standards, medical devices can be divided into active medical devices and passive medical devices, contact medical devices and contactless medical devices. After the release of the new *Classification Rules for Medical Devices* (hereinafter referred to as the "*Classification Rules*") in 2015, independent software (which is not attached to any hardware and can be used alone) has been included in a separate category of active contactless human devices[1]. The *Guiding Principles* also adhere to the spirit of the above provisions, clearly stipulating that independent software or software components themselves can constitute mobile medical devices[2].

According to the *Guiding Principles*, there is no clear demarcation line between mobile medical devices and ordinary mobile health electronic products. Any mobile computing device or software that qualifies the definition of medical devices shall be deemed as mobile medical devices. According to the *Classification Rules* and the *Independent Software Appendix*, **independent software** that qualifies the definition of medical devices is software that has one or more medical purposes and can accomplish its intended purpose on a general-purpose computing platform without medical device hardware; **software component** is software that has one or more medical purposes, controls and drives medical device hardware, or runs on a medical computing platform. Obviously, a medical health App that constitutes a medical device should have the core function of "medical treatment", and can provide services stated in its description or promotional materials through the App.

Take blood glucose meter as an example, the blood glucose meter monitors blood glucose by dripping blood, siphoning blood, or implanting a sensor under the skin. When it is not equipped with a "mobile computing terminal", it is not a mobile medical device. However, if a certain type of mobile blood glucose meter can transmit blood glucose data to the mobile phone through the audio port of the mobile phone, automatically record the blood glucose value measured by the user, form a blood glucose curve, and upload the data directly to the cloud, thus having blood glucose testing, data analysis, data sharing or intelligence reminders and other functions, then such mobile blood glucose meter should be regarded as a mobile medical device.

2. Determine a medical device by the function of medical health App

Traditional medical devices mainly perform their functions through physical means. Article 76 of the *Regulations on Supervision and Administration of Medical Devices* summarizes six major functions of medical devices: (1) diagnosis, precaution, monitoring, treatment or remission of diseases; (2) diagnosis, monitoring, treatment, remission or functional compensation of injuries; (3) testing, substitution, adjustment or supports to physiological structure or physiological process; (4) life support or maintenance; (5) pregnancy control; and (6) test of human body samples to provide information support for medical treatment or diagnosis. For the entire process of disease precaution,

[1] Article 5 of the 2015 "*Classification Rules for Medical Devices* (Decree No. 15)".
[2] Article 2 of the "*Guiding Principles* for the Technical Review of Mobile Medical Device Registration".

diagnosis, remission, and treatment, medical devices are important "tools" for medication professionals and people who need medical means to stay healthy. If the medical health App is expected to be used for diagnosis, treatment or monitoring of diseases, it should be recognized as a medical device, for example, an App that helps patients with rehabilitation training, treatment of obesity and autism; or an App for injury diagnosing and sample examination for "potential" patients. If an App is only targeted at healthy people, helping them with body-building or weight control, or merely lifestyle recording without any medical purpose, it should not be deemed as a medical device.

3. Compliance Management

For software that constitutes medical devices, China's regulators adopt the same classification and management system as traditional medical device registration. The new *Medical Device Classification Catalog* released in August 2017 further stipulates that if the artificial intelligence diagnostic software provides diagnostic suggestions with algorithms and only facilitates the diagnosis without directly giving diagnosis, it must be filed as a second class medical device (moderate risk); if the software can automatically identify the lesion and provide clear diagnostic suggestions, the risk level is relatively high and it needs to be managed as a third class medical device (relatively high risk). The second and third classes of medical devices are different in terms of control management, registration and business operation. For example, the second class medical devices are registered with the provincial medical products administration, while the third class devices are registered with the NMPA; the business operation of second class medical device follows filing system, while the third class medical device requires operating license from the city-level medical products administration.

In practice, mobile medical devices and health electronic products generally cannot be clearly distinguished. One medical health App may have diversified functions and provide differentiated services for different groups of people. The App operator must make case-by-case judgment on whether its App is a medical device, based on the definition of the medical device and the intended use of the medical health App. A filing must be made if an App constitutes a medical device. If the operator finds it difficult to make a determination, it is advisable for the operator to consult the NMPA for classification of medical devices. Once the medical health App is regulated as a medical device, in addition to the compliance risks inherent in traditional medical devices, operators should also consider the risks existed in the Internet environment. Especially, the operator must consider the environment for patient's use and their comprehension ability, in order to fully evaluate user's possible operational risks.

II. Compliance tips of medical health App advertisement

1. The particularity of medical health App advertisement

With regard to advertisements on medical health Apps, attention should be paid to their particularity from three aspects: the subject, content, and form. As far as the subject is concerned, App operators using the App platform to publish advertisements may act as advertisers, publishers, or advertising

operators. Content-wise, medical health Apps advertisements should not only comply with the general legal requirements on advertisements, but also meet the special regulatory requirements for publishing medical advertisements; regarding forms of advertisements, the advertisements published on the medical health App will be subject to the dual regulation for both ordinary media and online media.

As far as the subject is concerned, the operators can use medical health App as a new medium and platform to design, produce and publish advertisements themselves as advertisers. Moreover, entrusted by other advertisers, it can also provide agency services as an advertising operator. When the operator uses the App to publish advertisements, it becomes an advertising publisher. For example, a medical health App that helps users in weight control can either advertise their own fitness products or advertise as proxies for others' fitness products. Although these advertisements are presented to consumers through the same App, the operators bear different responsibilities depending on different roles. Generally, advertisers undertake the main responsibilities for an advertisement. For example, in case of making an advertisement of drugs, medical devices, health foods, and other advertisements on medical health Apps, advertisers must apply for an advertisement review. Where a false advertisement is published, advertisers would be punished while the advertising operator and publisher must provide the advertiser's real name, address, and effective contact information.

Regarding the form of medical health App advertisements, such advertisements are categorized as Internet advertisements. In 2015, the former State Administration for Industry and Commerce (SAIC) explained the highlights of the *Advertising Law*, clearly stating that the advertisement published by App is a new form of Internet advertising. It should comply with the special provisions of *Interim Measures for Administration of Internet Advertising* and the *Advertising Law* on Internet advertising. For instance, the advertisements shall not affect the normal use of the network by users[3]. In addition, the medical health app itself, as an advertising media, should comply with the general provisions of the *Advertising Law*, such as the prohibition of false advertisements. For the compliance analysis of Internet advertising, please refer to the author's another practical article titled *Analysis on the Identification of Illegal Advertisements*.

Content-wise, most of the advertisements published on the medical health App are related to medical services, drugs, and health products, and the current laws and regulations adopt a strict regulatory approach for medical advertisements. For instance, advertisements for narcotic drugs, psychotropic drugs, drugs for detoxification and medical devices are not allowed; the media where prescription drug advertisements can be published are strictly restricted. Even for medical, pharmaceutical, and medical devices that are allowed to be advertised, the content thereof cannot contain guarantees of efficacy, safety or cure rate, and hiring advertising spokespersons is not allowed. In addition, no matter what types of advertisements are published on the medical health App, they must meet the general requirements of the *Advertising Law*, such as no degrading the

[3] The Administration of Industry and Commerce explained the highlights of the amendments to the new *Advertising Law*: http://www.gov.cn/wenzheng/talking08/20150430ft99/wenzi.htm.
The last visit was December 23, 2019.

goods or services of other producers and operators. For drug advertisement compliance analysis, please refer to the author's another practical article titled *On the Compliance Risk of Medical Advertisements*.

2. Compliance tips

Apps operators should comprehensively and prudentially manage the advertisements and health information published on their Apps. First, an operator of a medical health App should determine its own identity when publishing advertisements and clarify the scope of responsibility. Second, regardless of the identity of the medical health App operator, the content of the advertisement should be examined to determine whether it is a medical advertisement, and whether the advertisement requires a pre-review, for example advertisements for medical services, drugs and medical devices specified in the *Interim Measures for Administration of Internet Advertising*. Moreover, it is essential to fully understand the special provisions of the *Advertising Law* on advertisements of different drugs, medical devices, and health foods. Except for medical services, drug and medical device advertisements, no other advertisements shall use languages suggesting treatment function or medical jargons, which mislead consumers to confuse the promoted product with drugs or medical devices[4]. In addition, Internet advertising can be made in a disguised form. For example, medical health Apps may include advertising information about related drugs or medical devices or attach videos or QR code of the similar advertising purpose when the Apps present health knowledge for users' education purpose. According to current law enforcement practices, medical information published in the aforesaid forms may still be considered as advertisements.

[4] Article 17 of the *Advertising Law*.

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