CHINA LAW UPDATE

AN UPDATE CRAFTED IN PRACTICE: THE NEW REGULATION ON MEDICAL DISPUTES

YAO Ziyi*

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* This note is prepared by YAO Ziyi, an LL.B. candidate at Tsinghua University School of Law.

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Ziyi Yao

I. INTRODUCTION & BACKGROUND

Since 2000, along with the continuous growth of medical services, the number and severity of medical disputes has been rising continuously.[1] For the purposes of preventing and addressing medical disputes, a number of normative documents have been issued.[2] Such documents aim, in particular, to address the verbosity of judicial redress, the hardship of obtaining compensation and the intensification of doctor-patient relationships.

Despite being the primary regulation applicable to medical disputes arising from medical accidents, the Regulation on the Handling of Medical Accidents has failed to address several outstanding problems in such medical disputes, some of which give rise to heated social discussions, such as the Yulin puerpera incident[3] and the Longgang "forced kneeling" incident[4]. Since the term "medical disputes" covers a wider range of cases than "medical accidents" and because the State Council deemed it necessary to summarize the judicial experiences of preventing and handling medical disputes, the Regulation on the Prevention and Handling of Medical Disputes, as the new regulation, was issued by the State

[1] *Sifabu, Weisheng Jiankang Wei jiu Yiliao Jiufen Yufang he Jiejue Tiaoli Da Jiezhe Wen* (*司法部、卫生健康委就《医疗纠纷预防和处理条例》答记者问*) [*Answering Journalists' Questions on the Regulation on the Prevention and Handling of Medical Disputes by Ministry of Justice and Nat'l Health Commission*], FAZHI RIBAO (法制日报) [LEGAL DAILY], Sep. 1, 2018, at 02.

[2] Normative documents include the Regulation on the Handling of Medical Accidents issued in 2002 by the State Council, the Notice of the Supreme People's Court on Trying Civil Cases on Medical Disputes by Referring to the "Regulation on the Handling of Medical Accidents" issued in 2003 by the Supreme People's Court, and Opinion on Strengthening the Role of People's Mediation in Medical Disputes issued in 2010 by the Ministry of Justice, the National Health Commission as well as the China Banking Regulatory Commission.

[3] On Aug. 31, 2017, a puerpera from Yulin, Shannxi chose to jump off a hospital building out of unendurable pain after her requests for a caesarean section were repeatedly rejected. *See Huigui Zunzhong Ningju "Chanfang Li de Gongshi"* (回归尊重 凝聚产房里的共识) [Cohering Respect: Consensus in the Maternity Ward], RENMIN RIBAO (人民日报) [PEOPLE'S DAILY] , Sep. 7, 2017, at 05.

[4] On Mar. 14, 2016, relatives of a 10-month-old deceased patient harassed the hospital and visiting staff by holding up banners, burning hell money, physically assaulting medical staff and forcing the visiting staff to kneel down and burn hell money for the deceased. *See* http://www.szhfpc.gov.cn/gzdt/201603/t20160316_3536235.htm (last visited Oct.8, 2018)

Council on July 31, 2018 and became effective on Oct. 1, 2018. This note will mainly introduce the advancement of the new regulation by comparing with the prior ones.

II. STRENGTHS OF THE NEW REGULATION

A. Delimiting the range of applications to the extent appropriate

The Regulation on the Handling of Medical Accidents (2002) was set out to handle "medical accidents", which refer to accidents caused by the negligence of medical institutions or their staff members that violates the laws, regulations and ministerial rules concerning medical treatment. However, for medical disputes that were not induced by violation of the regulations or where the patients were themselves liable, the 2002 Regulation was not applicable. In particular there was no recourse through the 2002 Regulation for cases of "violence against doctors" (aka *Yi Nao*),[5] where medical staff are often maliciously harassed or even assaulted by patients and/or *Yi Nao* gangs, looking to obtain compensation for actual or perceived medical malpractice.[6] The new regulation, therefore, defines "medical disputes" as disputes arising from diagnosis and medical care activities between medical institutions and patients.[7] Through including medical disputes where the patient may be liable, the new regulation can function as an amulet for doctors against unreasonable *Yi Nao*.

B. Heightening the role of mediation in medical disputes

Court proceedings may not always be a desired means given its high costs, time-consuming nature and exposure of private information. It is therefore not uncommon to see medical disputes being resolved by private settlement (*Siliao* 私了) without the

[5] The phenomenon of Yi Nao (医闹) has been identified as a contributing factor in violence against medical personnel. *See Violence against doctors in China*, WIKIPEDIA, https://en.wikipedia.org/wiki/Violence_against_doctors_in_China (last visited Nov.11, 2018).

[6] For "violence against doctors" that is severe enough to be incriminated, *see* Zhonghua Renmin Gongheguo Xingfa Xiuzheng An Jiu (中华人民共和国刑法修正案（九）) [Amendment (IX) to the Criminal Law of the People's Republic of China] (promulgated by the Standing Comm. Nat'l People's Cong., Aug. 29, 2015, effective Nov. 1, 2015) art. 31 (chinalawinfo).

[7] Yiliao Jiufen Yufang he Chuli Tiaoli (医疗纠纷预防和处理条例) [Regulation on the Prevention and Handling of Medical Disputes] (promulgated by the St. Council, Jul. 31,2018, effective Oct. 1, 2018) art. 2 (chinalawinfo).

support of reliable procedures. Mediation as a more formalized alternative dispute resolution mechanism is in the limelight of this round of medical reform.

The People's Mediation Committee for Medical Disputes, which was established with the approval from local judicial department and consists of experienced medical experts, legal counselors and professional mediators, is responsible for the mediation of medical disputes.[8] To guarantee the quality of the mediation service, the People's Mediation Committee for Medical Disputes is required to consult experts, conduct identification and evaluation of harm from medical negligence as well as to provide opinions.[9] Practices involving medical disputes in recent years has demonstrated that mediation, where a neutral third party reconciles two parties so that they compromise with each other, is an effective approach to mitigate doctor-patient conflicts and settle medical disputes, serving as a flexible means to address the disputes. For family or close friends that have lost their loved ones, mediation can ease their pain. Moreover, having a mediator is beneficial to protecting personal information that is inappropriate to be disclosed in court, so that both parties are less likely to suffer from cyber-violence and disturbance of the disputes will be mitigated. Furthermore, mediation provides a more cost-efficient way to settle disputes, saving time and money for both parties.

III. WRITTEN CONSENT REQUIREMENT IN RISK-RELATED SPECIAL MEDICAL CARE

In cases of emergency medical care related to risk or adverse effect, the new regulation clearly stipulates the requirement of consent as a prerequisite for the special medical care found in Article

[8] *Id*, at art. 31.
[9] *Id*, at art. 33, 34, 35, 36.

13.[10] If the patient is in a state of unconsciousness, medical operation or examination shall only commence with the consent of his or her relatives. In an emergency situation where doctors or medical staff are unable to obtain consent from relatives promptly, medical measures will be taken immediately after being approved by the heads of departments (referred to as "authorized persons in charge" in the regulation).

Under the previous regulations, doctors and medical institutions were often stuck in case of emergency. Such emergency situations require prompt measures, while consultations with the patients or their relatives would delay action on the part of the medical professionals. Where doctor took action without patient's prior consent, he may subject himself to legal liability in case of medical failure. This problem is partially addressed by Article 56 of the Tort Law of the People's Republic of China, issued on December 26, 2009, which provides that under emergency circumstances when the decision of the patient or his close relatives could not be obtained and the person in charge or the authorized person had approved the medical measure, courts shall not support patient's request for damages.[11] However, Article 55 of the Tort Law does not clearly define the scope of "special treatment and inspections", operations of which require the written consent of the patient. The new regulation specifies the term as having "certain risk" or "any adverse effect".[12]

IV. AFFIRMING THE POSITIVE FUNCTION OF MEDICAL LIABILITY INSURANCE

Article 7 of the Regulation requires that the medical risk allocation mechanism is to be established and advanced. Medical

[10] Article 13: Medical staff shall explain to a patient his or her state of illness and medical measures in diagnosis and medical care activities. If it is necessary to conduct operation or clinical experiment or any other special examination or special medical care that has certain risk and may cause any adverse effect, the medical staff shall explain the medical risks, alternative medical care plans and other information to the patient in a timely manner and obtain his or her written consent. Under the circumstance where the patient is in a state of unconsciousness or otherwise unable to make a decision independently or it is inappropriate to explain the state of illness to the patient, the medical staff shall explain to the close relative of the patient and obtain his or her written consent.

[11] Zhonghua Renmin Gongheguo Qinquan Zeren Fa (中华人民共和国侵权责任法) [Tort Law of the People's Republic of China] (promulgated by Standing Comm. Nat'l People's Cong.) art. 55 & 56 (chinalawinfo).

[12] *Supra* note 7, at art. 13.

liability insurance and accident insurance serve as a fundamental part of this mechanism.[13] While the medical accident insurance for patients resembles regular commercial personal insurance, the medical liability insurance, which covers damages and other legal fees caused by medical liability, will influence medical disputes in a more far-reaching way.

Known as "medical malpractice insurance" or "professional liability insurance" in developed countries such as the United States and Japan where medical institutions are generally insured, the medical liability insurance mitigates risk in the course of medical measures that are unlikely to be avoided or transferred.

Liability insurance is necessary for medical staff and institutions for the following reasons: Firstly, the medical industry is a high-risk industry, where unforeseen medical accidents occasionally occur. Secondly, the medical industry is of service nature. If medical accidents result in severe legal consequences, chances are that doctors will take a more risk-averse approach and avoid adopting risky medical treatments with a higher chance of success, leading to the shrinkage of service quality. Thirdly, in medication-related litigations, the reversed burden of proof renders the doctors and hospitals vulnerable.[14] One of the critical reasons that medical disputes are generally troublesome is the tense doctor-patient relationship, which is partly a result of the economic conflict between the two parties. With the introduction of medical liability insurance, a new compensation channel will be activated so that the tensions are likely to be eased.

[13] Xing Xueyi (刑学毅), Yiliao Jiufen Chuli Xianzhuang Fenxi Baogao (医疗纠纷处理现状分析报告) [Analysis Report on the Current Handling of Medical Disputes], 217 (2007).

[14] The reversed burden of proof is regulated in the Certain Provisions of the Supreme People's Court on Evidence in Civil Procedures (2008 Amendment Version), which requires that the medical institution should be responsible for proving the absence of any causal relationship between the medical act and the harmful consequences or it is not at fault. Zuigao Renmin Fayuan Guanyu Minshi Susong Zhengju de Ruogan Guiding (2008 Banben) (最高人民法院关于民事诉讼证据的若干规定（2008版本）) [Certain Provisions of the Supreme People's Court on Evidence in Civil Procedures (2008 Amendment Version)] (promulgated by Sup. People's Ct, Dec. 6, 2008) art. 4 (chinalawinfo).

In 2015, China proposed that by the end of 2015, all 3A[15] hospitals nationwide should be insured.[16] Recent policies also continue to encourage the purchase of medical liability insurance.[17] The new regulation reaffirms the policy of heightening the role of medical insurance system in handling and mitigating medical disputes. More advancement of the medical insurance system is likely to be seen in the future.

V. ENSURING PATIENTS' ACCESS TO MEDICAL RECORDS

As stipulated in Article 16 of the new regulation, patients have the right to consult and duplicate **all** of his or her medical records.[18] This is a breakthrough compared to previous regulations that only granted patients access to a portion of their medical records; the patient's right to be informed is now more materially protected.[19]

In the Regulation on the Handling of Medical Accidents, two types of medical records, referred to as "objective medical records" and "subjective medical records" respectively, are regulated distinctively.[20] Objective medical records are records that reflected

[15] 3A (Tertiary Level A) hospitals are the top hospitals in China. "Tertiary" hospitals refer to hospitals that provide high-quality professional medical service to multiple regions and conduct high-level education and research missions. "Tertiary Level A" hospitals refer to hospitals whose evaluation scores exceed 900 according to Sanji Zonghe Yiyuan Pingshen Biaozhun (三级综合医院评审标准) [Evaluation Standard for 3A Hospitals] (promulgated by Nat'l Health Commission, Apr. 22, 2011). *See* Yiyuan Fenji Guanli Banfa (医院分级管理办法) [Measures for the Administration of the Hospital Classifications] (promulgated by Nat'l Health Comm., Nov. 29, 1989).

[16] Guanyu Jiaqiang Yiliao Zeren Baoxian Gongzuo de Yijian (关于加强医疗责任保险工作的意见) [Opinions Regarding Strengthening Medical Liability Insurance] (promulgated by the Nat'l Health Commission, Jul. 11, 2014), http://www.nhfpc.gov.cn/yzygj/s3589/201407/65d55251804c408581a4e58db41f4bc7.shtml (last visited Oct. 8, 2018)

[17] *See* Guanyu Jianchi Yi Renmin Jiankang Wei Zhongxin Tuidong Yiliao Fuwu Gaozhiliang Fazhan de Yijian (关于坚持以人民健康为中心推动医疗服务高质量发展的意见) [Opinions Regarding Persisting Enhancing the High-quality Development of Medical Service Centering on People's Health] (promulgated by the Nat'l Health Comm., Aug. 16, 2018), http://www.nhfpc.gov.cn/yzygj/s3594q/201808/1e5aeaf3dbfb457487bc1d92783b43d8.shtml (last visited Oct. 8, 2018)

[18] Including medical records, hospitalization records, temperature sheets, medical order sheets, laboratory test reports (examination reports), medical image examination data, special examination consent form, operation consent form, operation and anesthesia records, pathological data, nursing records, medical expenses, and all other materials falling under medical records as prescribed by the health administrative department of the State Council.

[19] *See* Yiliao Shigu Chuli Tiaoli (医疗事故处理条例) [Regulation on the Handling of Medical Accidents] (promulgated by the St. Council, Apr. 4, 2002, effective Sept. 1, 2002) art. 10 &16 (chinalawinfo)

[20] *Id*.

objective medical conditions, such as patient's temperature, medical operations and anesthesia records. According to Article 10 of Regulation on the Handling of Medical Accidents, patients are able to acquire and duplicate their objective medical records. Subjective medical records, on the other hand, consist of an overall analysis of the state of illness observed as well as the patient's medical history, produced by medical personnel, and include minutes discussing deaths, minutes discussing difficult and complicated cases, records of looking after wards by doctors at higher levels, opinions of consultations and the records of the course of diseases. However, according to Article 16 of Regulation on the Handling of Medical Accidents, patients do not have access to the subjective medical records until the litigation phrase. Although the evidentiary effect of the subjective medical record during the course of litigation is still contentious, its unavailability places the patient in a disadvantageous position when dispute arises.

Thus the new regulation makes no distinction between objective medical records and subjective medical records. The previously regulated subjective medical records defined in the 2004 regulation are now redefined by the State Council as one kind of medical record and fall into the category of "other case history materials thereof as provided by the administrative department under the State Council in charge of health" of Article 10 of the Regulation on the Prevention and Handling of Medical Disputes. [21] This change ensures the patients' right to know and requires the medical institutions to provide high-quality service.

[21] Yiliao Jigou Bingli Guanli Tiaoli (医疗机构病历管理条例) [Regulation on Medical Records of Medical Institutes] (promulgated by the Nat'l Health Comm. & St. Administration of Traditional Chinese Medicine, Nov.20, 2013, effective Jan. 1, 2014) (chinalawinfo).