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Conceptual Analysis of Article 78 of the Medical Regulations of the Shenzhen Special Economic Zone of China on Advance Medical Directive

Bao Wei
Faculty of Law, The National University of Malaysia, Bangi, Selangor, Malaysia; p132454@ukm.edu.my

Nur Khalidah Dahlan
Faculty of Law, The National University of Malaysia, Bangi, Selangor, Malaysia

Mohd Zamre Mohd Zahir
Faculty of Law, The National University of Malaysia, Bangi, Selangor, Malaysia

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Abstract

Advance medical directive refers to arrangements made in advance by a competent individual, or the expression of their wishes regarding their medical care, in the event that they become incapacitated in the future. The development of a legal framework for advance medical directives in China is currently in its infancy. In June 2022, the Shenzhen Special Economic Zone in China amended the Shenzhen Special Economic Zone Medical Regulations to confer legal validity on advance medical directives. Prior to this, China had no formal legislation regarding advance medical directives. However, the legal definition of a Advance medical directive provided in Article 78 of the Shenzhen Special Economic Zone Medical Regulations is ambiguous, resulting in a lack of enforceability. This also hinders the further promotion of advance medical directives. This paper employs the methodology of legal doctrine to examine the concept of advance medical directive as set out in Article 78 of the Shenzhen Special Economic Zone Medical Regulations, analysing the legal attributes of this concept within the current Chinese legal system. It offers recommendations from a theoretical perspective regarding the issue of the ambiguity of legal provisions concerning advance medical directives in China.

Keywords: advance medical directives; living wills; the medical regulation of shenzhen special economic zone;will;contract

1. INTRODUCTION

Advance medical directive refers to arrangements made in advance by a competent individual, or the expression of their wishes regarding their medical care, in the event that they become incapacitated in the future. The system of advance medical directives originated in the United States in the 1990s. Under the influence of the United States, countries and regions around the world have begun to establish legal frameworks for advance medical directives. In the official legal texts of various countries, terms such as 'advance directives', 'advance medical directives' and 'living wills' have been used to refer to advance medical directives. In this article, the term 'advance medical directives' is used consistently to refer to the system of advance medical directives.When discussing legislation in various countries, the terms used are those found in the official legal texts of those countries. In 2022, China recognised the legal validity of advance medical directives for the first time through local legislation. In June 2022, the Shenzhen Special Economic Zone amended the Shenzhen Special Economic Zone Medical Regulations. Article 78 recognised the legal validity of advance medical directives through the concept of a 'living will', and set out the conditions for its validity and scope of application.A living will is a type of advance healthcare directive. There are two main types of advance medical directives: living wills and the appointment of a healthcare proxy. The appointment of a healthcare proxy serves as a valuable supplement and support to a living will. Should an individual lose the capacity to express their medical wishes, they may appoint a healthcare proxy to make medical decisions on their behalf. Both advance medical directives and the system of medical proxies require certain legal conditions to be met in order to be valid, and in practice, they are implemented in the form of legal documents. So what exactly is an advance medical directive? Is it a will? Or is it a contract? Or perhaps a power of attorney? If a legal dispute arises in connection with this legal document, what form of liability should be applied to resolve the dispute?Within China's civil legal system, legal concepts that are similar to, yet distinct from, advance medical directives include: wills, powers of attorney and contracts for medical services. A clear understanding of the concept of advance medical directives is a prerequisite for establishing dispute resolution mechanisms.From the perspective of refining the legal framework for advance medical directives, the conditions for their validity are linked to the criteria for determining an individual's legal capacity and to the validity of civil legal acts. Clarifying the concept of advance medical directives will facilitate an analysis of which legislative model is most suitable for China's current legal system. Specifically, this involves discussing whether it is more appropriate for China's national conditions to legislate on advance medical directives as a separate branch of law, or to incorporate them into the civil legal system by amending the existing Civil Code.

The United States is a prime example of a country that has enacted advance medical directives as standalone legislation. In 1976, the State of California enacted the Natural Death Act, which was the first piece of legislation to formally recognise the legal validity of advance directives; this Act subsequently influenced legislation in 40 other states. In contrast to the US legislative model, Germany, as a representative of civil law jurisdictions, chose to incorporate advance medical directives into the Civil Code by amending the Civil Code itself.In 2009, Germany amended its Civil Code (Amendment of Guardianship Law, 2009), introducing the concept of a 'living will' in Section 1901a to confer legal validity on advance medical directives. Provisions relating to advance medical directives were also incorporated into the chapter on guardianship, thereby integrating advance medical directives into the framework of the Civil Code.Although China has currently recognised the legal validity of advance medical directives through local regulations, the legal force of such regulations is limited (as they apply only within the Shenzhen Special Economic Zone), and the legal provisions are broadly formulated, with considerable ambiguity in their wording. From the perspective of legislative models, the aforementioned 'legislative practice' does not constitute a standalone legislative model, nor does it fall under the model of amending the Civil Code.

2. ADVANCE MEDICAL DIRECTIVES, LIVING WILLS AND THE SYSTEM OF MEDICAL PROXIES

The concept of advance medical directives originated with the living will. In 1969, the American lawyer suggested that people might plan their future medical care in advance by drawing on the concept of a will. This marked the birth of the living will.Advance directives draw inspiration from the systems of testamentary succession and estate distribution, but the legal relationship to which they pertain is that of healthcare provision. Subsequently,the United States began to promote and refine advance directives at the legislative level.In 1990, the US Congress passed the Patient Self-Determination Act, which clarified the legal status and validity of living wills nationwide and adopted the term 'advanced directives'. The Act also stipulated (I) the appointment of an agent or surrogate to make healthcare decisions on behalf of such an individual, and (II) the provision of written instructions concerning the individual's healthcare (including instructions for the disposition of organs).The 1990 Patient Autonomy Act established the system of medical proxies, positioning it as a vital complement to the advance directive system. Since then, advance directives (living wills) and the medical proxy system have together constituted the two main types of advance medical directives.

In the legislative context of advance medical directives, official legal texts in various countries use different terms to

refer to them. These include 'living will', 'advance medical directives' (or 'advance directive'). Whilst these concepts are related, they also differ; although the three terms vary in their wording, they essentially all confer upon competent patients the right to make advance arrangements regarding their future medical treatment.The legal basis for advance medical directives lies in patients' rights; whether referred to as a 'living will', 'advance directive' or 'advance medical directive', their legal validity is established on the basis of patients' rights. Patients' rights constitute an important component of fundamental human rights. Some researchers argue that patients' rights are constructed and extended from the foundation of fundamental human rights; given the professional and specialised nature of medical practice, patients' rights also possess specific attributes that distinguish them from general civil rights. Although patients are a specific category of legal person, they remain part of the broader category of civil subjects. Consequently, patients also enjoy general civil rights [1]. Given the specific nature of patients' rights, countries have enacted legislation addressing the specific content of these rights, with the aim of ensuring that the protection of patients' rights is aligned with actual medical practice. Examples include the 'Patient Rights Bill' drawn up by the American Hospital Association in 1972, and the 'Patient Rights Act' enacted by the US Department of Health, Education and Welfare in 1974.Building upon the legal framework for the protection of patients' rights, the United States has enshrined the concept of advance medical directives in law. From the perspective of legal interpretation and wording, a 'living will' and 'advance medical directives' (or 'advance directives') are distinct concepts, as they differ in both their scope and specific implications. In 1999, the State of Texas enacted the Advance Directives Act (Health and Safety Code). Section 166.002 [2] of the Texas Advance Directives Act defines "advance directive" as follows: (1) "Advance directive" means: (A) a directive as defined in Section 166.031; (B) an out-of-hospital "Do Not Resuscitate" (DNR) order as defined in Section 166.081; or (C) a health care proxy under Subchapter D.[1] According to this definition, an advance directive is a set of legal documents relating to a patient's personal medical choices, comprising three types of medical instructions: a living will, a medical power of attorney, and an out-of-hospital DNR order. As the country where advance medical directives originated, the United States uses the term 'advance directive' in its legal texts to refer collectively to a 'living will' and the 'medical power of attorney' system.

In addition to the United States, Germany also incorporated advance medical directives into its Civil Code in September 2009 through an amendment to the Civil Code. In Germany, advance medical directives are referred to as 'living wills'. Section 1901a of the German Civil Code defines a living will as a written declaration by an adult capable of giving consent, in which they specify the medical measures they wish to receive should they lose their capacity; these measures include specific examinations of their state of health, treatments or medical interventions that may be carried out in the future.A living will may be revoked at any time without having to comply with any formal requirements. The living will also appoints a guardian, who is responsible for assessing the suitability of the medical measures specified in the living will in light of the individual's current medical condition and for ensuring that the living will is carried out [3].[2] The German Civil Code uses the term 'living will' to denote the concept of an 'advance medical directive'. In contrast to the US, where the term 'advance directive' is used as a general term encompassing both 'living wills' and 'medical powers of attorney', the German Civil Code provides a more specific legal definition of the 'living will'. This includes specific details such as the eligibility requirements for drawing up a living will, formal requirements and rules governing revocation; it is no longer merely a generalised term.Section 1901a stipulates that no person is under any obligation to draw up a living will. The conclusion of a contract may not be made conditional upon the drawing up or submission of a living will. This establishes the 'living will' as a right rather than an obligation. From this perspective, a 'living will' is a legal document that embodies an individual's right to make autonomous choices regarding medical treatment. Furthermore, the German Civil Code distinguishes between a living will and a contract. A living will requires the legal capacity necessary for entering into a contract (full age and capacity to consent), whilst its specific content relates to an individual's arrangements regarding medical choices (an aspect that overlaps with a contract for medical services). However, a living will includes provisions whereby a patient may refuse life-sustaining treatment, an aspect that concerns the strict definition of criminal law.Criminal laws vary from country to country regarding euthanasia and assisted suicide; if the law permits passive euthanasia and assisted suicide, then a provision in an advance medical directive stating that the patient refuses life-sustaining treatment does not contravene the law. Conversely, if the law prohibits passive euthanasia and assisted suicide, an instruction in

[1] Section 166.002 of the Texas Health and Safety Code.

[2] German Civil Code section1901a-Living will (1) If a person of full age who is able to consent has determined in writing, for the event of their becoming unable to consent, whether they consent to or prohibit specific tests of their state of health, treatment or medical interventions not yet directly immanent at the time of determination (living will), the custodian examines whether these determinations correspond to the current living and treatment situation. If this is the case, the custodian is to see to it that the will of the person under custodianship is done. A living will may be revoked at any time without having to comply with requirements as to its form. (2) If there is no living will, or if the determinations of a living will do not correspond to the current life and treatment situation, the custodian is to determine the wishes with regard to treatment or the putative intent of the person under custodianship, and decide on this basis whether they consent to or prohibit a medical treatment pursuant to subsection (1). The putative intent is to be ascertained on the basis of concrete indications. Consideration is to be given, in particular, to previous oral or written statements, ethical or religious convictions and other personal values of the person under custodianship. (3) Subsections (1) and (2) apply regardless of the nature and stage of any illness of the person under custodianship. (4) Where appropriate, the custodian is to indicate to the person under custodianship the opportunity of establishing a living will and is to support that person, should they so desire, in establishing a living will. (5) No one may be placed under obligation to establish a living will. The conclusion of a contract may not be made contingent on the establishment or submission of a living will. (6) Subsections (1) to (3) apply to authorised representatives accordingly.

an advance medical directive to refuse life-sustaining treatment would contravene the law. The premise underpinning the above argument is how to define what constitutes life-sustaining treatment, and how a refusal of such treatment can be distinguished from passive euthanasia and assisted suicide. This is also the key distinction between advance medical directives and ordinary healthcare service contracts.

3. ADVANCE MEDICAL DIRECTIVES, WILLS, POWERS OF ATTORNEY AND GUARDIANSHIP

In law, a will, a power of attorney and agency are distinct legal concepts. A will refers to arrangements made by an individual during their lifetime regarding their property or other affairs; such arrangements must be made in accordance with the procedures prescribed by law. A will takes effect upon the death of the testator. A power of attorney, on the other hand, is based on an agreement between the principal and the attorney, whereby the attorney carries out civil activities within the scope of authority specified in the power of attorney. Agency, meanwhile, refers to a situation where an agent performs civil legal acts in the name of the principal within the scope of their authority.It is clear from the above definitions that wills, powers of attorney and agency all represent expressions of an individual's will. The distinction between the three lies in the scope and manner in which that will is exercised. A will is a document drawn up by an individual during their lifetime, setting out advance arrangements regarding their personal property and other matters. The concept of an advance medical directive draws inspiration from the systems of testamentary succession and property distribution; however, the legal relationship to which an advance medical directive pertains is that of medical services, unlike testamentary succession, which concerns the distribution of property rights and other affairs.Although both advance medical directives and wills involve an individual making arrangements for their personal affairs whilst still alive, there are significant differences in the specific content of these arrangements. Furthermore, a will only takes effect upon the testator's death, whereas an advance medical directive takes effect immediately upon being drawn up, provided it meets the statutory requirements.

Due to the vagueness and lack of enforceability of living wills, and the failure to account for situations where the testator loses capacity—rendering the living will unenforceable—the system of medical agents was subsequently established as an effective supplement to living wills. The United States was also one of the first countries to establish the system of medical enduring power of attorney, which originated from the concept of enduring power of attorney in US law. Under this system, a person of sound mind may appoint a trusted individual as their agent; should the patient subsequently lose capacity, this medical agent may continue to act on the patient's behalf in matters of medical care.The US system of medical durable power of attorney originated in the 1969 Uniform Probate Code. This code introduced the concept of durable power of attorney for the first time, extending the authority of the agent beyond the principal's loss of capacity. In 1979, the United States enacted the Uniform Durable Power of Attorney Act, which extended the concept of durable power of attorney to the various states; however, this Act stipulated that the scope of the power of attorney was limited to property rights and matters relating to property. It was not until 1983, when Pennsylvania and California (through the Durable Power of Attorney for Health Care Act) respectively enacted legislation on durable health care powers of attorney, that the scope of durable powers of attorney was extended to the field of healthcare at the legislative level.From general power of attorney to enduring power of attorney, and from enduring power of attorney to medical enduring power of attorney: this represents the innovation and development of the US legal system governing powers of attorney.

In summary, an advance medical directive differs from a will, a mandate and agency, yet it shares certain historical origins and connections with them. From a legal perspective, a mandate is a relationship established by contract between two parties on the basis of honesty and mutual trust. The mandatary performs obligations in their own name in accordance with the terms of the contract. Agency, on the other hand, comprises three types: contractual agency, statutory agency and appointed agency; both statutory and appointed agency are governed by law. Mandatory agency, on the other hand, is the product of the parties' free will. In agency, the agent conducts civil activities in the name of the principal. Whilst there are distinctions between mandates and agency, there are also connections; some forms of agency arise from a mandate relationship, but agency involves a tripartite legal relationship. Advance medical directives encompass the system of medical representatives. With regard to the system of medical representatives, when a patient appoints a medical representative, this may be done through either a mandate contract or an agency contract. Wills, mandates and agency, as legal concepts and fundamental principles of civil law, form the cornerstone of the development of the medical representative system and provide the specific pathways for its implementation.

4. ARTICLE 78 OF THE SHENZHEN SPECIAL ECONOMIC ZONE MEDICAL REGULATIONS: THE LEGAL NATURE OF ADVANCE DIRECTIVES

4.1. IS A LIVING WILL THE SAME AS A WILL?

In June 2022, the Shenzhen Special Economic Zone amended the Shenzhen Special Economic Zone Medical Regulations to incorporate the concept of 'advance medical directives' into the regional medical legal framework. Article 78 of the Medical Regulations of the Shenzhen Special Economic Zone stipulates that either the patient or their family members may submit an advance medical directive that meets the statutory requirements. Upon receipt of such a directive, hospitals shall respect the patient's expressed wishes when administering medical treatment during the terminal stage of an incurable illness or at the end of life.These are the statutory formal requirements for advance medical directives, which specifically include: 1. An advance medical directive must be notarised or witnessed by two or more witnesses, and the witnesses must not be healthcare professionals involved in the patient's treatment; 2. It must be made in writing or by audio or video recording. Except where notarised, if made in writing, it must be signed by the person making the advance medical directive and the witnesses, and the date must be stated; if made by audio or video recording, it must record the names or likenesses of the person making the advance medical directive and the witnesses, as well as the date.Article 78 stipulates that an advance medical directive must be notarised or witnessed, and must be in writing or recorded on audio or video, and must bear a signature and the date. The statutory procedures establish relatively strict requirements for the validity of advance medical directives, thereby distinguishing them from ordinary healthcare service contracts.In practice, standard medical service contracts are typically presented in the form of standard-form contracts, which set out specific medical services and associated risks in advance, in accordance with medical law and clinical procedures. When fulfilling their duty to inform, doctors will also explain these 'standard terms' to the patient, detailing the specific medical procedures and the associated risks. If the patient and their next of kin fully understand and accept these terms, they may sign the contract to confirm their agreement. Such general medical service contracts do not require procedures such as witnessing, notarisation, or audio or video recording.Furthermore, Article 78 is included in Section 2 of the Shenzhen Special Economic Zone Medical Regulations, which deals with standards for medical services; this indicates that, at the time of drafting the Regulations, advance medical directives were considered as part of the medical service process. However, due to the specific nature of the legal procedures and content of advance medical directives, they differ from general medical service contracts.

In addition to its strict legal procedures, Article 78 of the Shenzhen Special Economic Zone Medical Regulations is also distinctive in terms of its content, primarily in relation to the stages and scope of application of advance medical directives. In accordance with Article 78, when medical institutions administer medical treatment to patients in the terminal stages of an incurable illness or at the end of life, they must respect the patient's advance medical directive. In other words, it is only when a patient is in the terminal stages of an incurable illness or at the end of life that the patient's advance medical directive must be taken into consideration.With regard to the scope of medical interventions, patients have the right to choose whether or not to undergo invasive life-saving measures such as intubation and cardiopulmonary resuscitation (CPR), whether or not to use life-support systems, and whether or not to continue treatment for the underlying condition. Intubation and cardiopulmonary resuscitation (CPR) are invasive life-saving measures; even if they successfully save the patient's life, they may cause secondary trauma. Decisions regarding the use of life-support systems and the continuation or discontinuation of treatment for the underlying condition relate to whether the patient chooses to forgo life-sustaining treatment.The core value of the right to life is the sanctity of life. The Chinese Constitution grants every individual an equal right to life and health, and the law respects and protects the life of every person. Under the provisions of the Chinese Criminal Code, euthanasia and physician-assisted suicide are strictly prohibited; consequently, the content of an advance medical directive must not conflict with the legal principles of the Constitution and the Criminal Code. Therefore, the advance medical directive referred to in Article 78 of the Shenzhen Special Economic Zone Medical Regulations must be distinguished from a standard medical service contract.The Civil Code of China does not currently include specific provisions for medical service contracts as named contracts in Part III (Contracts); instead, it treats them as atypical contracts. Atypical contracts are to be interpreted in accordance with the general provisions of the Contracts section. In accordance with the general provisions of the Contracts section of the Civil Code of China, the parties, content and form of medical service contracts must all comply with legal requirements.Advance medical directives are a relatively new concept that has been introduced into China's existing legal system, and the Shenzhen Special Economic Zone Medical Regulations do not provide a definition of advance medical directives. Consequently, determining the legal nature of 'advance medical directives' has become a challenge. If it is not possible to define the legal nature of 'advance medical directives' or to reach a basic consensus on their interpretation, this will lead to difficulties in applying the law to disputes relating to 'advance medical directives'. So, is the 'advance medical directive' referred to in Article 78 a will? Is it a contract? If it is a contract, what type of contract is it?

4.2. IS A LIVING WILL A CONTRACT?

As Article 78 of the Shenzhen Special Economic Zone Medical Regulations does not define an 'advance medical directive', but merely sets out the statutory conditions for assessing its validity and its scope of application, it is not possible to define the legal nature of an 'advance medical directive' at the legislative level. Apart from the Shenzhen Special Economic Zone Medical Regulations, current Chinese law does not even include "advance medical directives" within its statutory provisions; furthermore, the Shenzhen Special Economic Zone Medical Regulations are valid only within the administrative boundaries of the Shenzhen Special Economic Zone. Although no legislative definition or template for an 'advance medical directive' can be found, the legal nature of the 'advance medical directive' referred to in Article 78 of the Shenzhen Special Economic Zone Medical Regulations can be examined by referring to the advance medical directive templates provided by the Shenzhen Advance Medical Directive Promotion Association and the 'Choice and Dignity' website, and by combining these with the findings of existing Chinese legislation and theoretical research.[3] The Shenzhen Advance Medical Directive Promotion Association defines an advance medical directive as a document signed in advance—that is, whilst the person is of sound mind—setting out the medical care they wish to receive or decline in the terminal stages of an incurable illness or injury, or at the end of life.[4] According to this definition, an advance medical directive is a document signed in advance, which individuals are required to sign whilst they are of sound mind. The specific content of the document concerns an individual's choices regarding medical care during the terminal stages of an incurable illness or injury, or at the end of life. As a document signed in advance, it is often likened to a will within the context of civil law.A will is also a directive document signed in advance; the main differences between an advance medical directive and a will lie in their effective dates, the content of the rights and obligations they entail, and the legal relationships they govern. Article 1133 [4] of the Civil Code of the People's Republic of China stipulates that a natural person may, in accordance with the provisions of this Law, make a will to dispose of their personal property and may appoint an executor. The legal relationship governed by a will is that of inheritance within the context of family law, and the subject matter is personal property. The legal relationship involved in an advance medical directive, however, is that of 'an individual's choice regarding medical care', namely the doctor-patient legal relationship between an individual and a medical institution.An advance medical directive governs medical treatment. In terms of when they take effect, a will comes into force upon the testator's death, whereas an advance medical directive takes effect immediately upon its execution. With regard to rights and obligations, a will governs the relationship between the testator and their heirs, whilst an advance medical directive governs an individual's medical rights and the obligations of healthcare providers. In summary, although both advance medical directives and wills are indicative documents left by an individual in advance, there are significant differences between the two in terms of the time of effect, the content of rights and obligations, and the legal relationships they govern.

In 1987, the State Council of China promulgated the 'Measures for the Handling of Medical Accidents', under which courts were required to resolve medical disputes through administrative channels. However, with socio-economic development and changes in medical practice, the administrative approach to resolving medical disputes has gradually become ill-suited to China's national circumstances. In 2002, the State Council of China promulgated the 'Regulations on the Handling of Medical Accidents', thereby repealing the 1987 'Measures for the Handling of Medical Accidents'. In terms of protecting patients' rights, the 2002 'Regulations on the Handling of Medical Accidents' provide stronger safeguards.In the early days, China tended to resolve medical disputes through administrative intervention. In academic research, some scholars have argued that the doctor-patient relationship constitutes an administrative legal relationship. The law stipulates that hospitals have a statutory duty to provide assistance and must unconditionally admit patients within the scope of their responsibilities. They also have duties such as assisting patients with transfers to other hospitals and arranging consultations. The establishment of the legal relationship between doctors and patients is not necessarily predicated on the voluntary consent of both parties; rather, it involves mandatory legal provisions and is subject to the constraints of public authority. Therefore, the doctor-patient relationship within the context of public, non-profit primary healthcare constitutes an administrative legal relationship [5]. With regard to the characterisation of the legal relationship between doctors and patients, in addition to the 'administrative legal relationship theory' represented by the scholar Hu Xiaoxiang, there are several other major schools of thought, including the 'civil legal relationship theory', the 'consumer legal relationship theory', the 'medical legal relationship theory' and the 'social legal relationship theory'. The 'civil

[3]The Shenzhen Association for the Promotion of Advance Directives was established on 26 March 2021, following review and approval by the Shenzhen Municipal Bureau of Civil Affairs. Under the guidance of the Shenzhen Municipal Health Commission and with the support of the Beijing Association for the Promotion of Advance Directives, the Association is a non-profit social organisation comprising enterprises, institutions and individuals dedicated to promoting the concepts of advance directives and palliative care. Website: Shenzhen Association for the Promotion of Advance Directives.

The Beijing Advance Directive Promotion Association (LWPA) was established on 25 June 2013. It is a public welfare organisation supervised by the Beijing Municipal Health Bureau and officially registered with the approval of the Beijing Municipal Bureau of Civil Affairs. The 'Choice and Dignity' website is the official website of the Beijing Advance Directive Promotion Association. Address: Home - My Five Wishes Registration Platform.

[4]See the official website of the Shenzhen Advance Directive Promotion Association, at: Advance Directives — Organiser: Shenzhen Advance Directive Promotion Association. Accessed on 5 June 2025.

legal relationship theory' is currently the prevailing view in academic circles.The doctor-patient relationship should not be simplistically categorised as a relationship between a consumer and a business operator. Neither the patient nor the hospital occupies the role of a pure consumer or business operator; rather, they should be regarded as two equal civil entities. The scope of civil legal relationships is broader than that of consumer-business legal relationships. The original legislative intent of the Consumer Rights Protection Law of the People's Republic of China was to safeguard consumer rights; consequently, the legal provisions are somewhat biased in favour of consumers. Logically, the doctor-patient relationship possesses the attributes of both a 'civil legal relationship' and a 'consumer legal relationship', with the two forming a relationship of inclusion and sub-inclusion [6]. The aforementioned view classifies the doctor-patient legal relationship within the broader scope of civil law, emphasising the equal standing of patients and healthcare institutions, whilst not denying that certain aspects of the doctor-patient relationship (such as the provision of health check-up services by health centres) possess the characteristics of a 'consumer-business relationship'. So, what implications would treating the doctor-patient relationship as a 'consumer-business relationship' have for patients?Seeking medical care is, in essence, a form of consumer activity. Article 2 of the Consumer Rights Protection Law of the People's Republic of China stipulates: 'Consumers whose rights and interests are protected by this Law are those who purchase, use goods or receive services for the purposes of daily consumption.' Daily consumption refers to the act of consuming goods or services to meet one's own needs for survival and development; therefore, when patients visit medical institutions, they are purchasing services from hospitals to meet their own survival needs [7]. By defining the legal nature of the doctor-patient relationship as a consumer legal relationship, the rights, obligations and legal status of both patients and healthcare institutions are correspondingly altered. Article 9 of the Consumer Rights Protection Law of the People's Republic of China stipulates: 'Consumers have the right to choose goods or services independently.' As consumers, patients have the right to choose their healthcare services independently. However, hospitals function as state health administrative bodies, and the law also imposes upon them a duty to provide emergency medical assistance to the general public. When a hospital fulfils its duty of emergency care, it is required to treat the patient even without the patient's consent. In such circumstances, the patient cannot exercise their right to choose as a consumer. Therefore, classifying the doctor-patient relationship purely as a consumer legal relationship does not meet the needs of specific medical practice in certain specific situations.Since the promulgation of China's Civil Code in 2021, legal relationships concerning medical services have remained within the scope of the civil law system. Medical service contracts are classified as atypical contracts, and Part VII, on Tort Liability, sets out provisions regarding patients' right to informed consent and healthcare institutions' duty to inform, establishing general principles governing the rights and obligations of both patients and healthcare institutions.Article 20(2) of the Consumer Rights Protection Law of the People's Republic of China stipulates: "Business operators shall provide truthful and clear answers to consumers' enquiries regarding the quality and methods of use of the goods or services they provide." In accordance with this provision, hospitals, as business operators, have a duty to provide patients with "truthful and clear answers" regarding the services they provide. The medical profession is a specialised one, and the scope of a doctor's duty to inform—taking into account the patient's condition—should be distinguished from the duty of a trader to inform a customer in the context of the sale of goods. "Truthful and clear answers" cannot be equated with "the content of a medical institution's duty to inform".If the doctor-patient relationship were viewed purely as a consumer legal relationship, this would lead to disputes and greater uncertainty when applying the law. Consequently, treating the doctor-patient relationship as a civil legal relationship provides a clearer basis for the application of the law and is better suited to the practical needs of the healthcare sector. Although Part Three of the Civil Code, which deals with contracts, does not specifically classify medical service contracts as named contracts, such contracts do meet the requirements of the general provisions on contracts and are therefore classified as unnamed contracts, that is, non-standard contracts.

There is currently no consensus within academic circles regarding the nature of medical service contracts, and the issue remains a subject of debate. The main point of contention centres on whether medical contracts are classified as named or unnamed contracts. From the perspective of named contracts, the majority of scholars argue that medical service contracts should be categorised as agency contracts. For instance, scholar Han Shiyuan contends that a medical service contract is one formed between a medical institution and a patient for the purpose of providing medical services; whilst there are distinctions between it and an agency contract, the two are also interconnected. Han Shiyuan proposes that medical service contracts and agency contracts should be viewed as being in a genus-species relationship, acknowledging that medical service contracts possess the fundamental attributes of agency contracts, whilst also recognising the specific characteristics inherent to medical service contracts themselves. Shiyuan, [8]. In addition to the 'agency contract theory', academic circles also propose the 'contract for services theory', the 'sale and purchase contract theory' and the 'lease contract theory'. Scholar Ning Lihong argues that treating all healthcare service contracts as agency contracts does not reflect the actual circumstances of medical practice. The content, nature and purpose of healthcare services vary; some services are fundamentally aimed at fulfilling the patient's needs, such as the fitting of dentures. Such healthcare service contracts possess the characteristics of a 'contract for work' [9].

5. DISCUSSION AND LIMITATION

Article 78 of the Shenzhen Special Economic Zone Medical Regulations stipulates that when medical institutions provide medical treatment to patients in the terminal stages of an incurable illness or injury, or at the end of life, they shall respect the patient's advance medical directive. When a medical institution receives an advance medical directive that meets the statutory formal requirements, and if the medical institution provides medical treatment in accordance with the instructions set out in the patient's advance medical directive, a legal relationship is established between the medical institution and the patient, with the patient's advance medical directive serving as the basis for that relationship. Within this legal relationship, the patient must be in the terminal stage of an incurable illness or injury, or at the point of death; this condition falls within the medical context. Furthermore, the medical interventions from which the patient may choose include: intubation, invasive resuscitation measures such as cardiopulmonary resuscitation (CPR), life support systems, and ongoing treatment for the underlying condition; these medical interventions form part of the services provided by medical institutions.A legal relationship is established between the doctor and the patient on the basis of an advance healthcare directive; the patient has the right to be informed and is free to choose medical treatments, whilst the healthcare institution has a duty to provide information and must respect the patient's freedom of choice. This reflects the contractual nature of an advance medical directive, whereby both parties express their genuine intentions and reach a consensus, each enjoying rights and fulfilling obligations in accordance with the agreement. Furthermore, the 'anticipatory' and 'directive' nature of an advance medical directive also possesses the attributes of a will, namely the making of arrangements and the expression of wishes regarding personal affairs or rights in advance. Whilst an advance medical directive possesses both contractual and testamentary attributes, it cannot be classified as a specific type of contract for the purposes of legal application, nor can it be treated as part of a will.The reason why advance medical directives cannot be classified as named contracts is that, although they possess the attributes of a contract, the legal relationships and subjects they govern are of a special nature. This is reflected in the scope of application of advance medical directives and the specific nature of medical choices, such as a patient's option to refuse life-sustaining treatment. As an indicative document, an advance medical directive pertains to specific medical procedures, and such procedures concern whether a patient may choose to forgo life-sustaining treatment or request assistance from others to end their life. This raises legal issues regarding passive euthanasia and physician-assisted suicide, which touch upon constitutional and criminal law principles.One of the prerequisites for the formation and validity of a civil contract is that its terms must not contravene the law. If the legal nature of an advance medical directive is defined as a contract, it is essential to consider the fundamental stance of the Constitution and the Criminal Law regarding the 'refusal of life-sustaining treatment', as well as the boundaries defining what is 'lawful' and 'unlawful'. Furthermore, an advance medical directive cannot be treated as part of a will. Article 1219 of China's Civil Code, as well as Articles 76 and 77 of the Shenzhen Special Economic Zone Medical Regulations, stipulate that a patient's close relatives have the right to be informed of the patient's medical condition and may make decisions on the patient's behalf when the patient is unable to do so [10].[5] Furthermore, in accordance with Articles 1045 and 1123 of the Civil Code, the patient's close relatives are also included among the statutory heirs [11].[6] Statutory succession refers to the process whereby, following the death of a patient, their close relatives begin to distribute the patient's lawful personal assets in accordance with the statutory order of succession. If the patient has left a will, testamentary succession takes precedence over statutory succession. If the patient's advance medical directive forms part of the will, the advance medical directive takes effect immediately upon its creation, meaning that it may be enforced even before the will comes into effect. Patients who are able to make an advance medical directive are typically in the terminal stages of an incurable illness or injury, or are approaching the end of life. The medical measures the patient may choose to use include life-sustaining treatment. It can be said that a patient's advance medical directive determines how and when they will complete the final journey of their life.Under the law, a patient's next of kin have the right to inherit the patient's estate and to make decisions regarding

[5] Article 76 of the Medical Regulations of the Shenzhen Special Economic Zone, China: Medical institutions and their healthcare personnel shall promptly explain to patients information regarding their condition, medical measures, medical risks and medical costs; where it is not possible or appropriate to explain such matters to the patient, they shall explain them to the patient's close relatives. Article 77 of the Medical Regulations of the Shenzhen Special Economic Zone, China In any of the following circumstances, medical institutions and their healthcare personnel shall promptly provide patients with specific explanations regarding medical risks, alternative treatment options and other relevant matters, and obtain their explicit consent; where it is not possible or appropriate to explain these matters to the patient, they shall be explained to the patient's close relatives, and their explicit consent shall be obtained: (1) where surgery, blood transfusion, anaesthesia, special examinations, special treatments, invasive medical cosmetic procedures, organ transplants or assisted reproduction are performed; (2) When administering a medicinal product in a manner not explicitly specified in the product information leaflet; (3) When conducting clinical research or clinical trials; (4) When prescribing medicinal products not included in the medical institution's drug formulary, or prescribing self-pay medicinal products for patients covered by medical insurance. In emergency situations, such as the resuscitation of a patient in critical condition, where it is not possible to obtain the consent of the patient or their close relatives, the relevant medical measures may be implemented immediately upon approval by the head of the medical institution or a person authorised by the head of the medical institution.

[6] Article 1045 of the Civil Code of the People's Republic of China provides that relatives include spouses, blood relatives and relatives by marriage. Spouses, parents, children, brothers and sisters, grandparents, maternal grandparents, grandchildren and maternal grandchildren are considered close relatives. Spouses, parents, children and other close relatives living together are considered family members. Article 1123: Upon the commencement of succession, the matter shall be settled in accordance with the rules of intestate succession; where there is a will, the matter shall be settled in accordance with testamentary succession or bequests; where there is an agreement on bequests and maintenance, the matter shall be settled in accordance with the agreement.

the patient's end-of-life medical care. Might this influence the motives behind the medical decisions ultimately made by the patient's next of kin? Factors such as the financial costs of the patient's treatment, the distribution of the patient's estate, and disagreements amongst the next of kin may all affect the effectiveness of the advance medical directive.

Article 78 of the Shenzhen Special Economic Zone Medical Regulations does not provide a clear legal definition of an advance medical directive; however, in practice, public interest organisations and social organisations offer online registration and completion services for advance medical directives. The 'Choice and Dignity' website, run by the Beijing Advance Medical Directive Promotion Association, has introduced a 'My Five Wishes' checklist as the main content for completing an advance medical directive. 'My Five Wishes' covers the following issues: 1. What medical services I do or do not wish to receive. 2. Whether I wish to use or decline life-sustaining treatment. 3. How I wish to be treated. 4. What I wish my family and friends to know. 5. Who I wish to assist me.[7] The five questions mentioned above do not relate to specific medical procedures or options available to patients; they are all rather general in nature. If no answer options are provided for each question, patients' responses will vary widely. The terms 'medical care' and 'life-sustaining treatment' are rather broad, and the sequence of the questions may lead to logical inconsistencies. If the patient selects 'medical care' in the first question, which includes a specific form of life-sustaining treatment, but then indicates in the second question that they do not wish to receive life-sustaining treatment, healthcare providers will face difficulties in implementing the patient's wishes.Article 78 of the Shenzhen Special Economic Zone Medical Regulations stipulates that when medical institutions provide medical care to patients in the terminal stages of an incurable illness or injury, or at the end of life, they shall respect the patient's advance directive. Patients may choose whether to undergo invasive life-saving measures such as intubation and cardiopulmonary resuscitation, whether to use life-support systems, and whether to continue treatment for their underlying condition. Terms such as 'intubation', 'cardiopulmonary resuscitation' and 'life support systems' are also open to interpretation.

Does the term 'intubation' referred to in Article 78 of the Shenzhen Special Economic Zone Medical Regulations refer to tracheal intubation as performed during cardiopulmonary resuscitation (CPR)? The term 'intubation' is overly broad and does not meet the standards of medical terminology; would medical institutions be able to understand the patient's wishes when reviewing their advance directive? Furthermore, if the term 'intubation' in Article 78 does indeed refer to tracheal intubation as part of cardiopulmonary resuscitation (CPR), then given the physical suffering and adverse effects that prolonged use of a tracheal tube may cause the patient, should the patient have the right to be informed of the consequences of such medical interventions or procedures when drawing up an advance medical directive? The question of who or which body should explain the relevant medical measures to patients who have drawn up advance medical directives and their close relatives is also an issue not addressed in Article 78 of the Shenzhen Special Economic Zone Medical Regulations. Life-support equipment is primarily used by hospital ICUs to help patients through critical periods, stabilise vital signs and promote recovery.Common life-support equipment in the ICU primarily includes ventilators, ECG monitors, blood gas analysers, infusion pumps, extracorporeal membrane oxygenation (ECMO) systems, continuous renal replacement therapy (CRRT) devices, bedside ultrasound machines, Positive End-Expiratory Pressure (PEEP) devices, and Central Venous Catheters. Furthermore, the term 'life support system' in Article 78 is overly broad. Based on the aforementioned equipment, life support systems can be categorised into three types: the first comprises vital signs monitoring devices, such as ECG monitors and blood gas analysers. The second category comprises devices designed to treat diseases and sustain life, such as extracorporeal membrane oxygenation (ECMO) and continuous renal replacement therapy (CRRT) devices. The third category consists of instruments that combine data monitoring and therapeutic functions, such as central venous catheters.A central venous catheter is a tube placed within a large blood vessel for the administration of drugs, fluids and nutrients, as well as for monitoring central venous pressure and haemodynamic parameters. Extracorporeal membrane oxygenation (ECMO), on the other hand, is a vital life-support technology used for patients with severely impaired respiratory or cardiac function, when conventional treatments are unable to sustain life. It is evident that life support systems encompass a variety of treatment modalities and the use of instruments and equipment. However, the definition of 'life support systems' in Article 78 of the Shenzhen Special Economic Zone Medical Regulations is broad. For Class III devices that combine data monitoring and treatment functions, opting to discontinue their use would imply that the treatment of the patient's condition would also be halted.As an indicative document, an advance medical directive may prove difficult to implement if it merely expresses the patient's medical wishes in a vague or general manner. There is a gap between medical expertise and the understanding of the general public; an advance directive is not a simple expression of intent. Its implementation relies on the patient's full understanding of and personal judgement regarding the medical measures they have chosen, as well as on whether the healthcare institution has fully discharged its duty to inform the patient and their close relatives. If an advance medical directive contains only vague instructions with unclear technical terminology, from a contractual perspective, this constitutes a lack of clarity regarding the rights and obligations of the contract, and the subject matter of the contract is insufficiently defined. From the perspective of a will, in accordance with

[7] See 'My Five Wishes' on the 'Choice and Dignity' website. Address: Home page – My Five Wishes registration platform

Article 1130 of the Civil Code of China, a will relates solely to the disposal of an individual's property [4].[8] The subject matter of an advance medical directive—namely, specific medical procedures—does not fall within the scope of a will. The distinctive nature of an advance medical directive lies in its regulation of medical procedures; take the withdrawal of life-sustaining treatment as an example. Can life-sustaining treatment be withdrawn? How should it be withdrawn? How should the patient's condition be managed following the withdrawal of life-sustaining treatment? These are all issues concerning legal principles and ethics. From the perspective of medical research, the withdrawal of life-sustaining treatment must comply with the requirements of medical ethics and professional practice guidelines.

Article 78 of the Shenzhen Special Economic Zone Medical Regulations does not provide a legal definition of 'advance medical directives', and the wording of the provision is ambiguous, rendering it unsuitable for practical application.Furthermore, the overall legislative framework of the Shenzhen Special Economic Zone Medical Regulations lacks a comprehensive system to safeguard and ensure the effective implementation of patients' advance medical directives; for instance, there is no system of medical proxies to address situations where patients lose their capacity. Furthermore, there is no comprehensive advisory system in place for the formulation of advance medical directives, leaving patients unable to fully understand the consequences of specific medical interventions or the legal implications of their own advance medical directives. The only formal legal text regarding advance medical directives in China is Article 78 of the Shenzhen Special Economic Zone Medical Regulations; however, as a local regulation, the Shenzhen Special Economic Zone Medical Regulations are only legally binding within the territory of the Shenzhen Special Economic Zone.In addition to the aforementioned formal legal texts, there are also unofficial public-interest organisations and social organisations (such as the Beijing Advance Medical Directive Promotion Association and the Shenzhen Advance Medical Directive Promotion Association) that promote and implement advance directives. These organisations provide online registration services for advance medical directives; individuals must first become members of the website before they can complete their advance medical directive. This paper also utilises the online advance medical directive template 'My Five Wishes' as a source of textual data for the study. In summary, the absence of formal legal texts regarding advance directives imposes limitations on the scope of the research and the effectiveness of its practical application. To broaden the scope of the research, a comparison of the legal texts on 'advance medical directives' or 'living wills' in the United States and Germany is undertaken to provide insights and a theoretical foundation for analysing the concept of 'living wills' as defined in Article 78 of the Medical Regulations of the Shenzhen Special Economic Zone. The United States and Germany were selected because the former, as the birthplace of the advance medical directive system, possesses a relatively comprehensive legislative framework and practical experience. Germany, as a representative of civil law jurisdictions, has incorporated the concept of the 'living will' into its civil law system through amendments to the Civil Code, integrating it with the guardianship system to form a distinctive legislative model for advance medical directives. China is also a country predominantly governed by civil law, and with the promulgation and implementation of the Civil Code in 2021, it has already laid the legislative groundwork for advance medical directives at the foundational level.

6. CONCLUSION

At the theoretical level, the concept of advance medical directives was initially inspired by the concept of a 'will'; as it developed and evolved, it incorporated elements of the systems of medical proxy and guardianship. This gradually gave rise to a framework centred on advance medical directives—or living wills—and supported by the system of medical proxies. An advance medical directive is not a will, nor can it be regarded entirely as a contract for medical services. The legal basis for advance medical directives stems from the extension of the right to privacy enshrined in the Constitution, namely the patient's right to autonomy. However, the right to personal freedom of choice cannot be exercised without restriction; where patient protection, national interests, public interests, and the protection of third-party rights are concerned, the law must impose limitations on an individual's right to autonomy. In this balancing of interests, the legal relationships established and governed by advance medical directives involve the intervention and involvement of state administrative power, thereby acquiring the nature of public authority. Consequently, they no longer fall entirely within the scope of civil legal relationships, such as healthcare service contracts.Article 78 of the Medical Regulations of the Shenzhen Special Economic Zone in China uses the term 'living will', but there is some ambiguity in its legal interpretation. The legal relationship governed by a living will is that between an individual and a healthcare institution, namely the individual's choices regarding medical care during the terminal stages of an incurable illness or injury and at the end of life. When a patient seeks medical treatment at a healthcare institution, the institution bears a statutory duty to inform. Once the patient is aware of their condition, they make corresponding choices regarding medical treatment, thereby establishing a legal relationship of rights and obligations with the healthcare institution.Although the Civil Code, which came into force in

[8]Article 1133 of the Civil Code of the People's Republic of China: A natural person may, in accordance with the provisions of this Code, make a will to dispose of their personal property and may appoint an executor. A natural person may make a will designating one or more of their statutory heirs to inherit their personal property. A natural person may make a will bequeathing their personal property to the State, a collective, or an organisation or individual other than their statutory heirs.

2021, does not include medical service contracts among the standard contracts in its Contracts section, this does not mean we can deny the contractual nature of the legal relationship between doctors and patients. In fact, as early as 2000, medical service contracts were recognised as a distinct category of contractual dispute, distinct from traditional medical liability disputes. The typical cases published in the 2004 'Bulletin of the Supreme People's Court' also included representative examples of medical service contracts, which further stimulated and advanced theoretical research and judicial practice relating to such contracts. The concept of a living will, as established by Article 78 of the Medical Regulations of the Shenzhen Special Economic Zone, cannot be denied as possessing the contractual nature of the doctor-patient legal relationship within the current Chinese legal system; however, a living will cannot be equated with a patient's last will and testament.

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