Legal Research on the Improvement of the Subject System of Advance Directives in China

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Abstract： As China's aging population intensifies (projected to reach 402 million people aged 60 and above by 2040, accounting for 28% of the total population), the issue of safeguarding autonomy in end-of-life medical decisions has become increasingly prominent. Article 78 of the Shenzhen Special Economic Zone Medical Regulations, which took effect on January 1, 2023, marks the first legislative confirmation of the advance directive system in China, representing a "breakthrough" in this field. However, significant deficiencies exist at the level of subject norms: ambiguous criteria for subject qualification, absence of mechanisms for assessing mental capacity, and undetermined subject status for special groups such as minors and individuals with cognitive impairments. These issues severely constrain the practical effectiveness of the system. This paper focuses on the core proposition of "improving the institutional subject," aiming to construct a normative framework for advance directive subjects that aligns with China's legal system and cultural context.

Keywords: Advance Directive; Subject Qualification; Medical Decision-Making Capacity; Shenzhen Medical Regulations

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1 Research Status and Foreign References

(1) Analysis of Deficiencies in Current Regulations

The pattern of China's advance directive system is that there is a lack of national laws and pioneering local pilot programs; although Article 33 of the Civil Code provides the legal basis for the "guardianship by designation" system of substituted decision-making, it needs to be activated by judicial declaration or notarisation. The guardian has the right to manage both the property and daily life of the minor; therefore, there is no advance directive for making medical decisions only. The Shenzhen Regulations have explicitly stated that medical institutions must respect the patients' stated wishes in advance directives for the first time; however, there are three serious flaws at the level of subject norms: First, the regulations do not specify the required standards for mental capacity to exercise advance directives. Practically speaking, there is a risk that the tripartite division of civil capacity (full, limited and absent) will be used blindly without considering the particularity of medical decision-making capacity, and thus overly strict standards will be imposed on behavioural capacity. Second, it is not provided for in the regulations whether minors and patients with Alzheimer's disease can make advance directives; thus, there is a regulatory gap for these special subjects. Third, there are no regulations for appointing agents to carry out advance directives; therefore, it is unclear who will make decisions for the patient after they lose the capacity to make decisions.

(2) Comparative Law References

The Uniform Health-Care Decisions Act in the United States is based on the concept of "medical decision-making capacity", and minors who can understand their own health problems and weigh the advantages and disadvantages of various choices (usually over the age of 14) are able to make advance directives. Germany has set up a dual-track system of "durable power of attorney" and "advance directive" in the Patientenverfügungsgesetz (Act on Advance Directives) to clarify the scope of agency. The above are references for improving the subject system in China.

2 Approaches to Improvement

(1) Construction of a "Tiered Standard" for Subject Qualification Determination

Therefore, it is proposed in this paper that we no longer use a single standard for civil capacity and will build a dual-tier determination system, making "civil capacity the foundation and medical decision-making capacity the exception". For ordinary subjects, the standard of full civil capacity will be applied to ensure the legal stability of advance directives. In special circumstances, there will be an evaluation of "contextualised medical decision-making capacity", and this will include the following: First, for young children in the progressive stage of illness, their age, level of maturity, understanding of the specific medical situation, and consistency in expressing choices will be taken into account; thus, it will be presumed that adolescents over the age of 14 do not have the capacity to make decisions about their own end-of-life care. Second, for patients with early-stage cognitive decline, standard cognitive screening tools (e.g., Montreal Cognitive Assessment) and function tests will be used to assess their ability to understand information about treatment choices, risks and benefits; although their capacity fluctuates, if they are lucid at some times, valid consent can still be obtained. The interdisciplinary team should consist of psychiatrists, attending physicians, clinical psychologists, members of the ethics committee, other social workers who know the patient's life and family circumstances, etc., and when necessary, the reasons for setting the scope of recognised capacity, which specific medical problems are covered, the expected validity period, mandatory reassessment times (e.g., every six months for deteriorating cases), etc., must be recorded in writing. A graded validity system will also be implemented; the directives issued in cases of reduced capacity will have preliminary legal effect and be under stricter supervision at first, but will only come into full force after some evaluation shows that the patient's condition is stable or that their will has not changed, thus balancing the protection of the vulnerable with respect for their right to self-determination.

(2) "Subject Articulation" of Proxy Decision-Making and Implementation of Advance Directives

To solve the problem of who can make decisions for a patient when they are incapacitated, an "advance directive agent" system will be

established to allow the declarant to appoint a medical agent in advance who is strictly authorised to carry out and interpret the provisions of the advance directive. The following institutional components will be specified: First, regarding the appointment procedure, the designation of an agent should be done in writing at the same time as or after the advance directive, stating the identity of the agent, scope of authority, hierarchical order of alternate agents and conditions for authority activation; the declarant can appoint multiple agents with joint or several authority and needs to inform these prospective agents in advance so that they can agree to serve. Second, for the scope of authority, the agent shall be authorised to: (a) access and interpret the advance directive in clinical situations; (b) communicate with the medical team about treatment decisions in line with the directive; (c) promptly make judgments when there is a discrepancy in the direct application of the directive; and (d) initiate judicial or ethical review procedures if the implementation of the directive encounters serious difficulties - but shall not have the right to modify, revoke, or ignore the main content of the advance directive. Thirdly, there should be a hierarchy for the standard of "substituted judgment" of agents: First, strictly comply with the explicit instructions in the advance directive; Second, if the issue is not covered by the advance directive, the agent should reconstruct the patient's former values, beliefs and preferences based on recorded conversations, religious beliefs, lifestyle choices and previous medical decisions, without using their own subjective judgment; Third, when the patient's values cannot be determined, objective "reasonable person" standards based on the patient's demographics and culture should be applied. Fourthly, if the above circumstances do not occur, under such circumstances, the concept of "best interests" will be further considered in light of the circumstances at the time the directive was issued; if the content of the advance directive is significantly inconsistent with the patient's actual interests - for example, due to new medical achievements that have shortened the disease course of people with terminal illnesses, because the original basis for making the directive was based on false information, or if it is determined that the unavoidable suffering resulting from a certain course of treatment is excessively large by others - then a special ethical review process shall be triggered within two days, which includes: (a) urgent discussion with the institutional ethics council and an external patient representative; (b) obtaining secondary medical opinions on changes in clinical conditions; (c) organising an orderly conference involving the designated person, family members, treating physicians, etc.; and (d) issuing a binding decision to either endorse the implementation of the directive, permit a deviation under specific circumstances with clear reasons, or suspend treatment until a judicial decision is made. The ethics committee's decision can be appealed to the special court within 7 days, and the burden of proof will be borne by the party challenging the applicability of the advance directive. In addition, to prevent abuse, the agent will be held to fiduciary duties of loyalty, care and confidentiality; if there is bad faith in interpreting or acting in conflict with interests, it will be deemed such; and based on a petition by the interested party, a court may revoke the agent if there is a significant deviation from the standard of substituted judgment.

3 Institutional Support and Path of Implementation

(1) Registration and Inquiry System

It is proposed to build one national electronic registration platform for advance directives, and this platform will be connected to the health record system and electronic medical record systems of citizens to provide timely information about changes in their conditions to relevant medical institutions. It would solve the problem of the "unlocatability and unrecognizability" of advance directives.

(2) Judicial Remedy Mechanism

The kinds of litigation for disputes over advance directives need to be specified, and the right to sue for "confirmation actions" on the validity of advance directives and objections to their implementation should be given to the declarants, close relatives and medical institutions. To speed up the process for the final decision, a shortened adjudication procedure will be implemented.

(3) Cultural Adaptation Adjustments

In response to China's familial tradition, a "family consultation preliminary procedure" shall be designed: After execution but before the commencement of an advance directive, medical institutions shall convene family meetings to explain the contents of the advance directive, record any objections, and determine whether such objections interfere with the implementation of the advance directive; at the same time, respect for family ethics and the protection of individual autonomy should be balanced.

4 Conclusion and Outlook

An improvement in the subject system of advance directives is needed to realise the legal guarantee of "dignity in death". This paper proposes that, in addition to the framework of guardianship by designation under the Civil Code, a special Advance Directives Law be enacted or a dedicated chapter be added to the Basic Medical and Health Care and Health Promotion Law to clarify the three main rules: tiered subject qualification, dynamic protection of mental capacity, and proxy articulation mechanisms. The Shenzhen pilot has shown that the implementation of institutions requires coordinated development of legal norms, medical practice and social cognition; as of April 2025, more than 20,000 people in Shenzhen have signed advance directives, but surveys show that only 23% of the public are aware of this system. Therefore, although improving the subject system is a first step, further work is needed in the future to build public opinion, professional training, case guidance, etc., to turn "rights on paper" into "dignity in practice".

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