

Legal Framework for Organ Transplantation and Protection of Donors and Recipients

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ARTICLE INFO

Article history:

Received 10 April 2025

Revised 02 May 2025

Accepted 14 May 2025

Key words:

Organ transplantation,
health law,
donor consent,
non-commercialization,
legal protection,
waiting list,
medical justice.

ABSTRACT

Organ transplantation is a life-saving medical procedure that requires a clear legal framework because it involves bodily integrity, donor autonomy, scarce resources, and potential commercial exploitation. This article examines the Indonesian legal framework governing organ transplantation through normative legal research using statutory and conceptual approaches. The findings show that Law Number 17 of 2023 on Health, Government Regulation Number 28 of 2024, and subsequent technical regulations establish a layered regulatory structure based on humanitarian purposes, non-commercialization, valid consent, donor protection, professional competence, institutional standards, and equitable recipient allocation. Living donors must provide voluntary and informed consent and meet administrative, medical, psychological, and socio-legal requirements. Deceased donation generally requires written family consent unless the donor expressed a valid willingness during life. Organ allocation combines medical urgency, compatibility, utility, family relationships, and waiting-list procedures. Legal certainty therefore depends on consistent implementation, reliable documentation, transparent allocation, competent facilities, and effective oversight. The framework seeks to protect donors and recipients while preserving transplantation as a humanitarian medical service.

INTRODUCTION

Organ transplantation is a medical procedure that enables the transfer of an organ from a donor to a recipient to address conditions where organ function can no longer be maintained through conventional therapy. Organ transplantation provides a life-saving opportunity and improves the quality of life for patients suffering from kidney failure, heart failure, and other organ diseases (Rezza et al., 2024). While advancements in transplantation expand opportunities for healing and life preservation, the procedure raises legal issues concerning medical personnel authority, donor status, consent, safety, organ allocation, and the prevention of commercial transactions (Lewis & Gardiner, 2023). The World Health Organization establishes donor protection, transparency, documentation, quality, and public trust as core elements of transplantation governance. These principles indicate that clinical success must be supported by legal certainty regarding how organs are procured and allocated. Human organs have a direct relationship with bodily integrity and

individual dignity; therefore, their transfer requires legitimate medical grounds, verifiable processes, and protection for vulnerable parties (Spiro et al., 2024).

Legal problems become more apparent when organ scarcity opens the way to payment, economic exploitation, coercion, and human trafficking. The Declaration of Istanbul on Organ Trafficking and Transplant Tourism places organ commercialism and the exploitation of vulnerable groups as problems that must be prevented through a transparent donation and transplantation system. The Declaration does not replace national law, but it provides an ethical framework that influences the formation of international standards on voluntary donation and the rejection of organ trading. Criminal law and professional ethics need to work together to deter abuse by health professionals (Hartika et al., 2023). This approach is relevant to the formation of health law because a person's consent does not by itself justify an organ transaction if the decision arises from economic pressure or power relations. Donor protection requires an examination of voluntariness

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together with limits that prevent organs from being treated as tradable commodities (Silva, 2023).

The regulation of transplantation in Indonesia changed after the enactment of Law Number 17 of 2023 on Health. This reform replaced the framework of Law Number 36 of 2009 and placed organ and tissue transplantation under more detailed regulation. There were normative changes in the provisions on the prohibition of commercialization, the authority of health care facilities, donor protection, and criminal sanctions. The change in law was then followed by Government Regulation Number 28 of 2024 as its implementing regulation. This Government Regulation revoked Government Regulation Number 53 of 2021 on Organ and Tissue Transplantation, so the legal assessment of transplantation procedures must now use the new regulatory structure. Changes in health regulation affect how well legal protection and access to services work in practice (Harianto et al., 2024). This reform requires a systematic reading so that older technical regulations are placed correctly within the applicable hierarchy of norms (Bakhtiar & Maddussila, 2024).

Consent is the central issue because organ removal touches a person's right over their own body and the medical risks that may continue after the procedure. This principle is realized through informed consent, which is a legal and ethical requirement before a medical procedure is performed (Susanti et al., 2024). Legal protection also needs to reach adverse events that appear after a medical procedure (Riyanto et al., 2023). Living donors need protection against coercion, inadequate information, and economic relationships that may affect the freedom of their decision. Poor communication of risks can expose health professionals to legal liability (Setiyadi et al., 2023). Deceased donors raise a different problem because the law must determine the relationship between the will once expressed by the donor and the authority of the family after death. Consent in transplantation therefore cannot be understood as a mere administrative signature (Raza & Neuberger, 2022). Its validity depends on capacity, voluntariness, information about risks, understanding of the procedure, and assurance that the decision is not a means of buying and selling organs. The norm of consent also relates to the obligation of health facilities to conduct medical, psychological, and socio-juridical examinations of prospective donors before transplantation is carried out.

The institutional aspect is equally important because transplantation requires medical and organizational capacity that is more complex than

routine care. The process includes the registration of donors and recipients, eligibility examination, compatibility testing, surgery, postoperative monitoring, documentation, and supervision. Each stage can produce legal consequences when the performer lacks authority, the facility does not meet standards, or administrative procedures are neglected. Clear boundaries of authority make it easier to enforce the law against violations by health personnel (Safitri et al., 2023). The transplantation system requires a division of responsibility among medical personnel, hospitals, the transplantation committee, and the government. Each party must understand its legal responsibilities so that patients remain protected (Setiawan et al., 2023). Certainty about this authority protects donors and recipients and also sets professional limits for medical personnel. Accountable implementation requires documentation that allows every clinical and administrative decision to be traced if a dispute, an alleged ethical violation, or an indication of a prohibited transaction arises later.

Organ scarcity also raises the question of fairness for prospective recipients. Not every patient in need of a transplant can receive an organ at the same time, so the law must determine priority criteria that are acceptable medically and legally. Considerations of medical need, compatibility, timeliness, family relationship, and waiting order can interact with one another. A system that relies too heavily on economic ability risks widening inequality, while a system that uses only waiting time may overlook the urgency of a patient's condition. Regulation must also keep access fair so that limited organs do not benefit only certain groups (Hartono et al., 2024). Legal certainty in allocation therefore requires criteria that are clear, transparent, consistent, and based on clinical assessment. Recording through an information system also has a legal function because it helps prevent the selection of recipients based on personal closeness or decisions that cannot be examined.

Legal study is still needed because the existence of a law and its implementing regulations does not automatically resolve all problems concerning the relationship among regulations. Minister of Health Regulation Number 38 of 2016 on the Implementation of Organ Transplantation is still recorded as valid, while part of the legal basis for its formation has changed. Clear regulation is needed so that patient safety and protection are not weakened by overlapping rules (Sasmita et al., 2023). Legal reading must determine the function of each rule so that there is no mixing among statutory norms, implementing provisions, technical requirements,

and operational guidelines.

This research is structured to elaborate the construction of principles and legal foundations for the implementation of organ transplantation within the framework of the Indonesian health legal system, while examining the hierarchical relationship between statutory laws and their implementing regulations. Furthermore, this study aims to analyze the consent requirements for both living donors and deceased donors as a manifestation of the protection of the donor's autonomy, safety, and freedom of will. Subsequently, the study is directed to examine administrative requirements, the jurisdictional boundaries of health service facilities and medical personnel, the institutional organization of providers, and the prohibition of commercialization practices along with the legal consequences arising from any violations thereof. Finally, this research intends to examine the mechanism for determining prospective organ recipients and the compilation of waiting lists based on the principles of justice, maximum medical utility, information transparency, and procedural certainty at every stage of organ transplantation implementation.

RESEARCH METHOD

This research is normative legal research employing statutory and conceptual approaches. Marzuki (2017) positions legal research as an activity to discover rules, principles, and arguments capable of resolving legal issues. Primary legal materials consist of Law Number 17 of 2023 on Health, Government Regulation Number 28 of 2024, Regulation of the Minister of Health Number 38 of 2016, and ministerial decrees related to deceased donation and transplantation institutions. Secondary legal materials, in the form of legal books, bioethics articles, international guidelines, and transplantation studies, are utilized to clarify the principles of consent, justice, donor protection, and the prevention of commercialization. The statutory approach is employed to examine the arrangement of authority and obligations, whereas the conceptual approach is used to assess the relationship between autonomy, humanity, justice, and legal protection.

The collection of legal materials was conducted through literature studies, after which the materials were classified according to the four research objectives. Soekanto and Mamudji (2015) anchor normative legal research on the examination of written legal materials, while Ibrahim (2006) emphasizes the reading of norms within a systemic relationship to ensure that provisions are not isolated from their legal structure. The analysis was

performed through grammatical, systematic, and conceptual interpretations. Provisions regarding the objectives of transplantation were examined alongside norms concerning donors, healthcare facilities, registration, consent, eligibility screening, waiting lists, and sanctions. The status of regulations was verified to ensure that repealed rules were not utilized as operational bases. Ethical literature served as a conceptual comparative benchmark rather than a substitute for national norms. The interpretive results were subsequently structured prescriptively to elucidate the legal positions of the parties involved and the elements required for legal certainty in the implementation of organ transplantation.

RESULT AND DISCUSSION

Basic Principles and Legal Basis of Organ Transplantation

The main framework for organ transplantation lies in Law Number 17 of 2023 on Health. The Law revoked Law Number 36 of 2009 and several other health laws, so references to the old regulation should be treated as part of legal history, not as an operational basis. Transplantation is placed as part of the delivery of health efforts and receives specific provisions on its purpose, types of donors, determination of death, health care facilities, allocation principles, stages of implementation, and the rights of recipients. These provisions affirm the importance of the principles of non-discrimination, benefit, and justice in health services (Noor et al., 2023). This structure shows that the legislators did not regard transplantation as an ordinary surgical procedure. It requires a special legal regime because it involves the transfer of a part of the human body, risks to the donor, organ scarcity, and the need to protect patients who depend on the service. Clear and consistent rules help prevent gaps in implementation (Khayru et al., 2024), and a special regime is needed so that patients receive legal protection in health services (Tampil et al., 2023). The status of Law Number 17 of 2023 is still recorded as valid in the national regulatory database (Bakhtiar & Maddussila, 2024).

Article 124 of the Health Law places the purpose of transplantation on curing disease and restoring health, and limits it to humanitarian purposes. This norm is an initial limit on the motives that the law accepts. The transfer of an organ is normatively valid when the procedure is directed at the medical needs of the recipient and carried out through the health service system. The following paragraph prohibits organs and body tissues from being commercialized or traded for any reason. The Elucidation of the Law distinguishes the commercialization of organs from

the costs of health services that lawfully arise in the implementation of transplantation. This distinction is needed because transplantation still requires funding for examinations, surgery, medication, care, and monitoring. The prohibition is aimed at turning an organ or the act of donation into an object of profit that contradicts the humanitarian purpose, not at medical costs that have a service basis. Financial practices that deviate from lawful service can give rise to the legal liability of health facilities (Eskandar et al., 2025).

The Law distinguishes donors into living donors and deceased donors. A living donor is a person whose organ is removed while still alive with their own consent. A deceased donor is a person whose organ is removed after being declared dead by medical personnel at a health care facility with written consent from the family, unless the donor expressed willingness to be a donor during their lifetime. Article 126 recognizes two bases for determining death, namely clinical or conventional death through the permanent cessation of heart function and circulation, and brain stem death or brain death. This division gives certainty about when the law permits organs to be removed from a deceased donor. Consent given by the donor or the family must be assessed carefully so that the decision remains legally accountable (Susanti et al., 2024), and the right of a person to refuse must also be respected (Khayru et al., 2025). The determination of death must be conceptually separate from the interest in obtaining organs so that the decision on death remains based on medical standards that can be accounted for (Batubara et al., 2021).

Article 127 reinforces the principle of legality in implementation by providing that transplantation may only be performed at health care facilities and by medical personnel who have the expertise and authority. The facility must meet the requirements set by the Minister. This norm binds two elements at once, namely the place of implementation and the person performing the medical procedure. Fulfilling one element does not replace the other. A competent doctor must still work through a facility that meets transplantation standards, while a hospital that has received designation cannot hand the procedure to personnel who lack the required competence and authority. Competent personnel are the basis for service quality and consistent performance (Darmawan et al., 2020). This limitation protects patients from services carried out through facilities that lack adequate laboratory, surgical, intensive care, infection control, and postoperative monitoring support, as well as a sufficient transplantation support system.

Article 128 provides a substantive framework for transplantation decisions by listing the principles of justice, medical utility, compatibility of the organ with the recipient, priority order according to medical need or family relationship, timeliness, organ characteristics, and the health of the living donor. This arrangement shows that no single consideration can stand alone. The needs of the recipient must be balanced with the safety of the donor, biological compatibility, and the likelihood of clinical benefit. The principle of justice also limits decisions so that social status or non-medical relationships do not displace the criteria set by law. This provision gives a legal basis for a selection system that combines medical considerations and fairness. A transplantation decision must therefore be explainable through indicators related to clinical need and eligibility, not through the informal preferences of the provider.

The stages of transplantation in Article 129 include the registration of prospective donors and recipients, donor eligibility examination covering the procedural, psychological, and socio-juridical aspects, compatibility testing, surgery, and postoperative management. This norm shows that surgery is only one stage in the whole legal and medical process. Psychological and socio-juridical examinations have special meaning because the condition of a donor cannot be assessed by medical parameters alone. Voluntariness, the relationship with the recipient, possible family pressure, economic conditions, and indications of a transaction must be examined before an organ is removed. The postoperative stage also extends the responsibility of the facility because the safety of the donor and recipient does not end when the surgery is completed. Documentation of every stage serves as a means of proof that the procedure was carried out according to standards if a legal problem arises after the transplantation. Medical records are an important piece of evidence that can show whether the procedure was carried out properly (Ustani et al., 2024).

Government Regulation Number 28 of 2024 functions as the implementing regulation of the Health Law and has been in force since 26 July 2024. One of its legal consequences is the revocation of Government Regulation Number 53 of 2021 on Organ and Tissue Transplantation. This consequence needs attention in legal writing because the substance that was once in Government Regulation 53/2021 must now be read through Government Regulation 28/2024. The transplantation part of the new Government Regulation details donors, the family members who may give consent, registration,

administrative requirements, eligibility examinations, the determination of death, the relationship between donor and recipient, and the waiting list. Its inclusion in the implementing regulation of the Health Law also places transplantation as part of the national health service system, which is connected to facilities, medical personnel, health information, and supervision. Clear implementing rules also help ensure that disputes arising after a procedure are handled with proportionate legal measures (Fanani et al., 2025).

Minister of Health Regulation Number 38 of 2016 on the Implementation of Organ Transplantation is still recorded as valid. Its validity must be read systematically together with Law Number 17 of 2023 and Government Regulation Number 28 of 2024, because the ministerial regulation was issued when the health law structure still relied on the old law. The principle of hierarchy requires that a provision of a ministerial regulation not be used if it conflicts with a higher and newer norm. The parts that remain consistent can function as technical rules of implementation, including those on transplantation management and institutions that have not been specifically replaced. Rules from different sectors must be read together so that they do not contradict one another in practice (Ambarwati et al., 2024). This approach is more appropriate than treating the regulation as automatically invalid merely because its statutory basis has changed, as long as it has not been revoked and there is no normative conflict with the new provisions.

The legal framework also distinguishes organ transplantation from body tissue transplantation, although both are placed in adjacent parts of the regulation. Differences in biological character, method of acquisition, risk, storage, and use can produce different technical requirements. A study that focuses on organs needs to maintain this boundary so that rules on tissue, eye banks, or other biological material are not applied directly to organs without a basis. Separating the legal objects helps determine the relevant facility requirements, allocation system, and registration procedures (Kwisda, 2023). In interpretive practice, the term "organs and/or body tissue" used by the law must still be read according to the object under discussion. A clear distinction between objects also makes it easier to determine who is responsible when an error occurs (Alex et al., 2023). This terminological discipline contributes to legal certainty because a kidney or liver transplant has a different service character from the transfer of a cornea or certain tissue.

The right to become a recipient is also recognized through Article 130 of the Health Law. Every person in principle has the right to become a recipient, while the determination is based on medical emergency or survival and is carried out fairly, transparently, and responsibly. This right cannot be interpreted as an absolute right to obtain an organ immediately because donor availability and medical compatibility remain factual limits. Its legal meaning is that every prospective patient who meets the indications must obtain access to the assessment process according to the same rules. Access to health services must be distributed equally (Khayru & Issalillah, 2022), including for patients with rare or costly conditions (Rahawain et al., 2024). Differences in social background must not become a basis for unequal treatment in access to services (Amri & Khayru, 2022; Mardikaningsih, 2021). A decision to reject or postpone needs medical and procedural reasons that can be explained (Babini et al., 2023). Clear information about costs and risks also helps patients understand the reasons behind such a decision (Rachim et al., 2024). The recognition of the recipient's right also affirms the duty of the provider to ensure that the selection process is not controlled by economic capacity, social status, or closeness to the facility.

The legal framework of transplantation can be understood as a structure of layered protection. The law sets the purpose, prohibitions, rights, principles, and basic sanctions. The government regulation details the procedures for donors, recipients, registration, examination, death, and allocation. Ministerial regulations and ministerial decrees provide technical standards, institutional arrangements, and service guidelines. This division allows general norms to be translated into administrative actions that hospitals can carry out. Risk arises when implementers know only one layer of rules (Rathi, 2023). A hospital that refers to technical regulations without paying attention to changes in the law may use procedures that are no longer aligned, while reading the law without implementing rules can be too general for operational needs. Profit orientation in hospital management must not reduce fair access to services (Amalia & Issalillah, 2025), and legal protection for patients must remain available when personnel make mistakes (Lethy et al., 2023). Justice can be realized by balancing the patient's right to autonomy with the ethical and moral responsibility of the hospital to provide safe and quality health services (Sugianto et al., 2023). Internal harmonization is the responsibility of providers, regulators, and the health

legal personnel who accompany the service.

The legal framework of transplantation rests on humanitarian purpose, the prohibition of commercialization, donor safety, justice for recipients, medical authority, and the legality of facilities. Law Number 17 of 2023 is the main source, Government Regulation Number 28 of 2024 details its implementation, and Minister of Health Regulation Number 38 of 2016 can still be used as long as it is consistent with higher and newer rules (Bakhtiar & Maddussila, 2024). This structure forms the relationship between ethical principles and legal obligations. Humanity does not remain an abstract value because it is translated into the prohibition of buying and selling, consent, donor examination, the waiting list, and limits on who may perform the procedure. Consent must also be accompanied by an explanation of risks so that the legal liability of each party can be determined clearly if a problem arises after the procedure (Amir et al., 2024). Legal certainty is achieved when every layer of rules is read according to the hierarchy and used according to its normative function.

Consent of Living and Deceased Donors as Legal Protection

Living donor consent is a form of exercising autonomy and also a legal requirement for organ removal. Government Regulation Number 28 of 2024 affirms that a living donor gives an organ while still alive based on their own consent. A violation of a person's right to decide over their own body creates a need for legal protection (Nur et al., 2025). The legal relationship between giver and recipient in organ transplantation is not a commercial agreement, but is based on voluntariness without compensation (Mubasyiroh & Issalillah, 2023). The registration rules then require a minimum age of eighteen years, a written statement of willingness to donate an organ voluntarily without asking for compensation, family consent, an understanding of the indications, contraindications, risks, the transplantation procedure, and postoperative life guidance, as well as a statement that the donor has not entered into a sale or an agreement that implies payment. This structure shows that valid consent requires more than the ability to say "agree". The law demands proof of voluntariness, information, and the absence of a transaction. Administrative requirements function as a preventive instrument before an organ is removed (Purwaningsih, 2020).

The freedom of a living donor's decision needs to be examined because family relationships can produce pressure that is hard to see. Decisions on

medical procedures are made after the patient has received adequate information (Chairul et al., 2023). A prospective donor may not face any explicit threat but may feel guilty if they refuse to help a family member. Biller-Andorno et al. (2001) place free and informed consent as the ethical basis for living donation and show the need for additional evaluation when voluntariness is in doubt. This perspective matches the psychological and socio-juridical examinations required by national law. Examiners need to distinguish acceptable altruistic motives from decisions that arise through pressure, economic dependence, or fear of family sanctions. The presence of a close relationship is no reason to reduce caution. Such a relationship can instead make the evaluation of voluntariness more complicated because pressure may arrive through unspoken social expectations.

Informed consent requires adequate understanding of the risks to the donor. These risks may include surgical complications, recovery, temporary changes in work capacity, monitoring needs, and possible long-term medical consequences depending on the type of organ. Information should be given in language that can be understood and should give prospective donors a chance to ask questions. Consent signed after an overly technical explanation can still be challenged if the donor did not understand its substance. The ethics of living donor evaluation emphasize voluntariness, disclosure of risks and benefits, donor suitability, and protection against hasty decisions. Legal and medical examinations need to complement each other so that the consent document reflects a process of communication and does not replace that communication (Wall et al., 2021). Recording the explanation in the medical record shows that the communication actually took place (Mubarak et al., 2023).

Family consent for a living donor functions as an additional layer of protection in Government Regulation Number 28 of 2024. This requirement does not remove the position of donor consent as the main basis because the organ comes from the body of a living person. Family consent is better understood as a mechanism of social verification and assistance, not as a right to force the donor. If the donor refuses, the family cannot replace their decision. Conversely, if the donor agrees but signs of pressure or a transaction appear, the existence of family consent is not enough to make the process valid. The hospital is still required to carry out an eligibility and socio-juridical assessment. Professionalism requires health workers to act quickly for patient safety, while the

principle of autonomy requires respect for the patient's right to decide what is done to their own body (Feriadi et al., 2023). This interpretation maintains a balance between individual autonomy and protection against the risks that may arise from family relationships.

The prohibition of compensation has a direct relationship with the validity of consent. A decision that appears voluntary in form can hide a payment agreement between donor and recipient. For this reason the Government Regulation requires a written statement that the prospective donor does not sell the organ and does not make an agreement that amounts to sale or payment. This requirement gives hospitals a basis to ask for clarification about the relationship between donor and recipient, including circumstances that raise suspicion of a transaction. The examination should not assume that all non-family donors are selling, but it must be able to detect inconsistent patterns. Fair treatment requires that an evaluation rest on facts, not on assumptions about a person's background (Napu et al., 2024). Donor protection requires procedures that respect privacy while still ensuring that the decision is not the result of economic exploitation (Prasetyo et al., 2023).

A deceased donor has a different structure of consent. The Health Law and Government Regulation Number 28 of 2024 provide that the removal of organs from a person who has died in principle requires written consent from the family. The family referred to includes the husband or wife, an adult child, the biological parents, and biological siblings. This arrangement gives a clear identification of the parties with authority so that hospitals do not ask for consent from people who have no basis of relationship under the regulation. Clear identification of who may decide protects the family and also helps the hospital avoid disputes later (Maulidiyandi et al., 2024). Accuracy in identifying the family is part of legality because the decision to remove organs must not depend on a party who is merely present at the hospital without a recognized position.

The rules give stronger respect to the donor's will when that person, during their lifetime, has declared willingness to become a donor. In such a case, transplantation can be carried out after death without family consent. This norm recognizes a personal decision made when the donor was still able to determine their will. Legally, this position strengthens autonomy because the family is not given the authority to cancel a valid donor statement. The administrative challenge is to ensure that the earlier statement can be verified and was truly made by the person concerned (Albertsen,

2020). The donor recording system needs to be able to produce clear evidence of identity and willingness so that hospitals do not face uncertainty when the time for organ removal is very limited. Hospitals also need to be ready to act promptly when time is short (Mohamad et al., 2024).

Siminoff, Agyemang, and Traino (2013) show that consent policies for deceased donors are closely related to communication practices with families and to the design of the donation system. This literature teaches that the legal aspect needs to be backed by sensitive communication procedures because donation requests are often made when the family is grieving. The explanation of death, the possibility of donation, and the basis of consent should be given separately and clearly so that the family does not see the determination of death as influenced by the interest in obtaining organs. This separation helps maintain public trust and keeps the family's decision free.

Consent of a deceased donor is also related to the diagnosis of death. Government Regulation Number 28 of 2024 provides that the diagnosis of brain stem death or brain death is made by at least two specialist doctors who are not involved in the transplantation procedure, consisting of an anesthesiology specialist and a neurology specialist, with the possible involvement of other specialists when needed. Separating the team that determines death from the transplantation team prevents conflicts of interest. The decision that a person has died must be made because the medical criteria for death are met, not because there is a prospective recipient. This norm has a major protective function for donors and families because the determination of death becomes an independent legal prerequisite before organs are removed. An error in diagnosis can give rise to a duty to compensate those affected (Mokoginta et al., 2024).

Decree of the Minister of Health Number HK.01.07/MENKES/1033/2024 provides guidelines for the implementation of transplantation using brain stem dead or brain dead donors. The Decree was issued to improve access to and quality of services and to give operational guidelines on the use of donors who meet these criteria of death. The presence of the guidelines clarifies that the recognition of brain death in the law and the Government Regulation requires consistent service standards in hospitals. The application of the guidelines must remain under the norms of consent, identification, donor eligibility, and the prohibition of commercialization. Technical guidelines do not reduce the rights of the family or the will of the donor as regulated by law, but help facilities carry out

procedures after the legal and medical bases are fulfilled (Batubara et al., 2021).

Consent documentation serves both evidentiary and supervisory functions. Hospitals are required to retain donor statements, family consent where mandated, risk disclosure outcomes, eligibility assessments, and records of the team's decisions. Such documentation protects both donors and recipients by clarifying the information provided and the stages undertaken. For medical personnel, documentation establishes the legal basis of authority to perform procedures involving organ retrieval. For regulators and supervisors, this audit trail enables inspection in the event of suspected coercion, trafficking, or non-compliance with requirements. Complete documentation does not inherently prove that the process is entirely free of issues; however, incomplete documentation can impair the system's ability to ensure voluntarism and accountability.

Donor consent is a legal process that integrates autonomy, protection, information, and verification. For living donors, individual consent serves as the primary foundation, supplemented by age requirements, voluntary declarations, family consent, risk disclosure, and anti-trafficking declarations. For deceased donors, family consent functions as the general rule, whereas a valid expression of the donor's will during life can supersede the requirement for family permission after death (Lewis & Gardiner, 2023). The diagnosis of death must be performed according to established criteria and by medical personnel independent of the transplantation team. This structure ensures that organs are procured through legitimate decisions rather than coercion, transactions, or abuse of circumstances. Robust protection relies on the quality of communication and documentation rather than mere consent forms alone.

Administrative Requirements, Institutions, and the Prohibition of Commercialization

The registration of prospective donors and recipients is the administrative gateway that connects medical need with the transplantation system. Government Regulation Number 28 of 2024 sets the administrative requirements for living donors and recipients so that the process can be traced from the beginning. A prospective recipient needs a statement from the attending doctor on the indication and the absence of contraindications, must understand the risks and the procedure, must give consent, and must declare that they have not bought an organ or entered into an agreement that implies payment. These requirements show that the prohibition of

commercialization applies in both directions. The law requires the donor to state that they do not sell the organ, and it also asks the recipient to affirm that they do not buy. This mechanism builds an administrative basis for assessing the relationship between the parties before the medical procedure is carried out. A prohibition works only when it is accompanied by sanctions that can be enforced (Sirenden et al., 2024). A person's psychological condition affects how well they understand risks and make decisions (Khayru & Issalillah, 2022), and patients' rights must be respected throughout the process, including the right to understand their condition (Mengga et al., 2024).

Administration must not be seen as a formality separate from safety. The identity of the donor, the relationship with the recipient, the examination results, and the consent determine whether the process can continue. If a donor declares a family relationship, the statement of that relationship needs to be verifiable. The Government Regulation requires a statement of blood relationship or marriage from the regional apparatus responsible for population and civil registration for donations intended for certain family members. This verification has an anti-abuse function because family relationship affects the waiting list mechanism. Falsification or inaccuracy of relationship status can change the position of a recipient and harm other candidates. For this reason the validity of administrative documents has a substantive effect on the fairness of allocation. Orderly administration is a basis for managing health services (Vitrianingsih et al., 2022), and accurate documents protect patients, as users of services, from losses caused by false information (Indaryanti et al., 2023).

The facility requirements for organ transplantation in hospitals continue to be refined along with the strengthening of the risk-based business licensing framework in the health subsector. The Ministry of Health plans to issue a Minister of Health Regulation on Business Activity Standards and Product/Service Standards in the Implementation of Risk-Based Business Licensing in the Health Subsector, which includes the implementation of organ transplantation in hospitals as a Business Licensing for Sustaining Business Activities (PB UMKU). The presence of this regulation will update and consolidate the hospital licensing framework that was previously spread across various licensing regulations in the health subsector. A hospital as an institution bears responsibility for errors committed by its personnel (Mening et al., 2023), and facilities that fail to meet standards can be held accountable (Wahyusetiawan et al., 2024; Sopyan et al., 2024).

Facility standards are needed because organ transplantation is a multidisciplinary and high-risk service. It is not enough for a hospital to have an operating room; the implementation of transplantation requires a transplantation outpatient clinic, ancillary laboratory services, an intensive care unit, an adequate pharmacy system, advanced diagnostic capability, postoperative care services, and a structured quality management and patient safety mechanism. Strengthening hospital internal regulations through the formation of a medical committee and audits of incidental cases can help improve legal protection for patients (Maulidiyandi et al., 2024). Organizational effectiveness depends on adequate resources and clear procedures (Darmawan, 2024), and the quality of service influences how patients assess the care they receive (Darmawan et al., 2022; Mardikaningsih, 2022). From the perspective of health administrative law, the fulfillment of facility and human resource standards is a normative requirement for granting and maintaining the authority to provide services. A hospital that has not met these requirements cannot use the competence of an individual doctor as a legal basis for carrying out transplantation. The legality of transplantation services is attached to the combination of professional competence and institutional eligibility as one unified licensing requirement.

The role of medical personnel also needs to be placed within the structure of professional authority. Complex examination and care create a medical relationship and also a legal relationship between medical personnel and patients, which requires systematic accountability (Kholis et al., 2023). The Health Law requires transplantation to be performed by medical personnel who have the expertise and authority. This authority covers the professional aspect, the practice license, the hospital's internal credentialing, and procedural competence according to standards. Acting beyond one's authority creates legal risk (Subhi et al., 2023; Vitrianingsih et al., 2023), and doctors who act in an emergency also need clear legal protection (Juliarto et al., 2023). In complex services, decisions usually involve several disciplines, so responsibility does not rest entirely on the surgical operator. The doctor who assesses the donor, the personnel who determine death, the recipient's doctor, the anesthesiologist, laboratory staff, nurses, and other teams have different functions. Decisions made together work better when each party has the same information (Darmawan, 2024). The division of tasks needs to be set out in hospital procedures so that the line of accountability is clear. A system that relies on

informal habits can make assessment difficult when an unexpected event or a dispute arises over who should have carried out a particular examination (Mercado-Martínez et al., 2015).

Administrative oversight functions to prevent violations from escalating into criminal offenses. Hospitals are empowered to examine document completeness, identity validity, assessment results, donor-recipient relationships, and information flows indicating potential transactions. The transplantation committee or team may suspend procedures when material ambiguities arise. Such internal mechanisms afford an opportunity to prevent organ procurement before harm occurs. If suspected criminal acts are discovered, internal procedures do not supersede the authority of law enforcement agencies. A clear functional separation is necessary to ensure that hospitals do not conduct criminal investigations independently, while still preserving evidence and reporting in accordance with available legal mechanisms (Lira & Torres, 2024).

Record-keeping and reporting are equally vital for national oversight. Systems storing data on donors, recipients, types of transplantation, examination outcomes, and follow-ups assist regulators in identifying service patterns and detecting irregularities. Data must be managed alongside the obligation to maintain medical confidentiality and protect personal information. Transparency in transplantation does not entail public disclosure of donor or recipient identities without legal basis; rather, it ensures that institutional processes are auditable and decision criteria can be examined. A balance between accountability and confidentiality is essential to prevent oversight from infringing upon patient privacy rights (Geissler et al., 2023).

Legal protection represents the state's effort to guarantee rights, security, and legal certainty fairly, based on prevailing legal provisions and humanitarian values in society (Nurhefi et al., 2023). Legal protection in transplantation relies on the interrelation among administrative requirements, hospital standards, medical personnel competence, national institutions, supervision, and sanctions. The prohibition of commercialization is reinforced through administrative declarations by donors and recipients, alongside criminal penalties stipulated in the Health Law. An effective system requires pre-transplantation screening, intra-procedural documentation, and post-service supervision. This approach ensures that the objective of healing remains inseparable from the legality of how organs are procured and services are rendered.

Waiting Lists, Recipient Justice, and Procedural Certainty

Organ scarcity requires the law to regulate more than individual medical eligibility. When multiple recipients are in equal need of transplantation, providers must determine who receives an organ first. Law Number 17 of 2023 provides a foundation through the principles of justice, medical utility, compatibility, medical need, family relationships, timeliness, organ characteristics, and donor safety. Government Regulation Number 28 of 2024 further details the mechanisms governing donor-recipient relationships and waiting lists. This structure demonstrates that allocation is simultaneously a normative and clinical decision. Physicians evaluate need and compatibility, whereas the law establishes boundaries to prevent decisions from turning into choices based on personal closeness, ability to pay, or irrelevant social considerations (Bakhtiar & Maddussila, 2024).

Government Regulation Number 28 of 2024 distinguishes donors who have a blood relationship or a marital relationship with the recipient from donors who do not. Blood relationship covers the biological father, biological mother, biological child, and biological sibling. Transplantation from a donor who has a blood relationship or is a legal spouse of the recipient does not require the general waiting list (Bakhtiar & Maddussila, 2024). This mechanism is understandable because the living donor has been directed to a specific person through a verified family relationship. The absence of a waiting list does not mean the process is free from examination. The donor must still meet the administrative, medical, psychological, and socio-juridical requirements and must be free from any transaction. Orderly administrative rules keep the process traceable from the start (Vitrianingsih et al., 2022).

For donors who have no blood relationship with the recipient, implementation follows the waiting list. The order of the list takes into account the recipient's medical need and uses an organ or tissue transplantation information system integrated with the National Health Information System. Medical need can become the basis for setting priority. This mechanism places a limit on direct donation to non-family parties, which could open the way to choosing a recipient based on payment or informal relationships. By placing non-family donors into the waiting list system, the law shifts the decision from personal relationships toward a mechanism that can be held accountable.

Records of waiting list decisions can serve as evidence if a dispute arises later (Ustani et al., 2024).

Persad, Wertheimer, and Emanuel (2009) show that the allocation of very scarce medical resources cannot be settled by a single simple principle. Equality, priority for those most in need, maximization of benefit, and social considerations can produce different results. In transplantation, this explains why a waiting list cannot rely only on the order of registration. A patient whose condition worsens quickly may need higher priority than a patient who has waited longer but remains stable. At the same time, medical benefit needs to be considered so that the organ goes to a recipient who is compatible and likely to gain clinical benefit. Indonesian law, which combines justice, medical utility, need, and compatibility, reflects such a multi-principle approach.

Petrini (2015) shows that organ allocation policies in various systems face the need to balance clinical criteria and ethical principles. Justice, clinical usefulness, and waiting time can carry different weights depending on the policy. The lesson that can be drawn is the need to state the criteria openly so that prospective recipients understand the factors that determine priority. If the weight of medical need changes without clear information, the system can be regarded as inconsistent. Transparency does not mean that every detail of the algorithm must be simple, but the normative and clinical reasons that form the order need to be explainable.

The principle of justice also relates to access to the waiting list. A person who theoretically has the right to become a recipient has not obtained a real opportunity if they are never referred to a transplantation center, have difficulty obtaining examinations, or cannot complete the administrative requirements. The literature on organ allocation places access to the waiting list as a prerequisite of justice because a priority system applies only to people who have entered that mechanism. Geographic and economic factors can affect a patient's ability to reach a transplantation center. The development of referral networks and public information therefore has legal relevance because it helps the recipient's right to be realized through more equal access to evaluation (Ferreri, 2023). Access to health services needs to be distributed equally across groups (Khayru & Issalillah, 2022).

Data from the Ministry of Health currently list hospitals that have transplantation services and show that the service is available through a number of facilities in various regions, with different types of transplantation. Open information on facilities

helps prospective patients and health workers know where to refer. The distribution of services still needs to be viewed together with the needs of the population because transplantation requires high-capability facilities that cannot yet be available in every region. Referral policy needs to provide a path so that regional limitations do not automatically close a patient's chance to obtain an evaluation. A patient's right to appropriate care must remain protected even when services are limited by location (Mengga et al., 2024).

Allocation decisions also need to avoid social discrimination. Occupational status, wealth, popularity, political position, or a person's social value are not listed as a basis for priority in the Health Law. Legitimate considerations are directed at medical need, utility, compatibility, family relationship for certain donations, and timeliness. This limitation has a protective meaning because organs are a very limited health resource. A decision that gives privilege based on non-medical status would be difficult to justify within a framework of justice. Patient rights require equal treatment regardless of a person's social standing (Sugianto et al., 2023). Information systems and documentation can help ensure that changes in order have reasons that can be examined (Bobbert & Ganten, 2013).

Procedural certainty requires that prospective recipients know the stages they must follow, the documents needed, the basis of the examination, and the reasons for decisions. Unclear procedures can produce gaps even when the substantive norms are fair. A patient with better access to information will find it easier to meet the requirements than a patient who depends on limited explanations (Jonas et al., 2014). Clear information is the basis of valid consent and of accountable decisions (Susanti et al., 2024), and legal protection for patients includes the right to understand the process they go through (Tampil et al., 2023). Hospitals need to provide communication that is easy to understand about registration, compatibility testing, eligibility evaluation, changes in waiting list status, and follow-up. This information must still distinguish between the right to take part in the process and a guarantee of obtaining an organ. Donor scarcity makes the final result impossible to guarantee, but the procedure for obtaining a fair chance must be understandable.

Information systems have an additional function as an anti-commercialization instrument. When non-family donors and recipients are managed through an official list, the room for private agreements that decide the recipient can be narrowed. The system can record registration time,

medical condition, compatibility, and changes in priority so that decisions are easier to audit. The reliability of the system depends on data quality and access security. Recording errors can change the order and cause serious harm (Niyigena et al., 2020). A hospital may bear liability for recording errors that harm patients (Maulidiyandi et al., 2024). Information governance must therefore have clear correction and authorization mechanisms. The use of technology does not remove human responsibility because medical decisions still require professional evaluation.

Justice in allocation needs to be balanced with medical utility. A very limited organ is better used when there is compatibility and a chance of benefit that can be justified. The principle of utility does not mean giving the organ to a person regarded as socially "more valuable". The term relates to the medical benefit of transplantation, including the likelihood that the organ will function and help sustain the recipient's survival (Ferrerri, 2023). Justice protects opportunity and distribution, while medical utility protects the safe and rational use of organs. The tension between the two needs to be resolved through criteria set in advance, not through ad hoc decisions after an organ becomes available. Such decisions must be made by those who have the authority and according to the criteria that have been set (Subhi et al., 2023).

The national allocation system integrates donor relationships, waiting lists, medical needs, compatibility, justice, and medical utility. Family or spousal donors can be directed straight to a specific recipient after all requirements are met, whereas non-family donors follow a waiting list linked to the health information system (Heemann et al., 2020). Legal certainty requires explainable priority criteria, fair access to transplantation evaluation, documentation of status changes, and a ban on discrimination based on non-medical factors. Procedural transparency strengthens trust and helps prevent private transactions that bypass the queue. Ultimately, transplantation justice does not mean every patient receives an organ at the same time, but rather that every prospective recipient is processed through consistent, medically relevant, and accountable rules.

CONCLUSION

The legal framework for organ transplantation has established a layered normative structure through Law Number 17 of 2023, Government Regulation Number 28 of 2024, ministerial regulations, and ministerial decrees governing technical and institutional aspects. This system positions

humanitarian objectives, the prohibition of commercialization, consent, donor safety, medical authority, facility legality, and recipient justice as interconnected elements. Living donation requires voluntary consent, information, administrative verification, and protection against transactions. Deceased donation requires criteria for determining death as well as family consent, unless a valid willingness was expressed during life. Hospitals and medical personnel must meet competency standards, while organ allocation is guided by medical need, compatibility, utility, specific donor relationships, and waiting lists. Legal certainty depends on the consistent application of rules and the documentation of every stage of implementation.

Juridically, regulatory reform requires hospitals, medical personnel, transplantation managers, and legal researchers to apply rules in accordance with their hierarchy and enforcement status. Government Regulation Number 53 of 2021 is no longer appropriate for use as an operational basis following its revocation by Government Regulation Number 28 of 2024, while Regulation of the Minister of Health Number 38 of 2016 must be interpreted in harmony with newer regulations. Institutionally, procedures for consent, donor assessment, waiting lists, documentation, and reporting form part of legal protection rather than standing as isolated administrative obligations. Ethico-legally, donor autonomy remains constrained by the principle of safety and the prohibition of commercialization. This construction reinforces service legitimacy when every decision possesses verifiable medical and juridical foundations.

Transplantation providers must periodically update internal procedures to ensure that all forms, examination standards, consent mechanisms, and waiting list governance comply with Law Number 17 of 2023, Government Regulation Number 28 of 2024, and the latest technical regulations. The government can strengthen socialization regarding donor registration, recipient rights, transaction bans, and the status of donor intent expressed during life. Hospitals need to provide psychological and socio-legal assessments capable of detecting coercion or economic relationships without stigmatizing non-family donors. The transplantation information system must be equipped with auditing mechanisms, data correction protocols, and confidentiality protections. Subsequent legal research can focus on the practical implementation of waiting lists, the oversight of suspected commercialization, and procedural consistency across hospitals to evaluate the alignment between written norms and their execution.

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