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THE REALIZATION OF THE PRINCIPLE OF LEGAL CERTAINTY IN REGULATIONS ON KIDNEY TRANSPLANTATION FROM LIVING DONORS AFTER THE ENACTMENT OF LAW NUMBER 17 OF 2023 CONCERNING HEALTH

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Abstract. *Kidney transplantation from living donors is a life-saving medical effort for patients with end-stage renal disease that requires comprehensive legal protection. This study aims to analyze the legal framework for the protection of living donors in kidney transplantation based on Law Number 17 of 2023 concerning Health, identify the implementation of the principle of legal certainty in transplantation practices, and formulate challenges and recommendations to enhance the effectiveness of legal protection. The research method uses a normative-juridical approach by analyzing legislation, bioethical principles, and practical implementation in the field. The results show that Law Number 17 of 2023 has provided a strong legal foundation through comprehensive regulations regarding informed consent, donor requirements, prohibition of organ commercialization, and integrated oversight mechanisms. However, its implementation still faces challenges such as regulatory complexity, limited inter-agency coordination, resource gaps, and socio-cultural factors. This study recommends strengthening oversight mechanisms, vertical and horizontal regulatory harmonization, institutional capacity building, and the development of an integrated national transplantation information system to ensure optimal protection for living donors.*

Keywords: Kidney Transplantation, Living Donor, Legal Certainty.

INTRODUCTION

Kidney transplantation is a definitive therapy for patients with end-stage renal disease (ESRD), offering a better hope for life compared to long-term dialysis therapy. In Indonesia, the prevalence of chronic kidney disease continues to increase along with the rise in diabetes mellitus and hypertension as the main risk factors. Data from the Indonesian Nephrology Association shows that more than 50,000 patients require renal replacement therapy each year, but the number of kidney transplants performed remains very limited, averaging only about 200-300 cases per year (Pernefri, 2013).

Kidney transplantation from living donors has advantages over deceased donors, including higher success rates, better kidney function, and shorter waiting times. However, this

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procedure raises complex ethical and legal dilemmas because it involves invasive actions on a healthy individual (the donor) for the benefit of another individual (the recipient). This paradox requires a strong legal framework to protect the rights of donors while still facilitating access to life-saving therapy.

The enactment of Law Number 17 of 2023 concerning Health, which replaces Law Number 36 of 2009 concerning Health, brings a new paradigm in the regulation of organ transplantation in Indonesia. This law comprehensively regulates the transplantation of organs and body tissues in Chapter XIII, Part Five, specifically Articles 263 to 267, which are further elaborated in Government Regulation Number 53 of 2021 concerning Organ and/or Body Tissue Transplantation.

The implementation of legal protection for living donors faces multidimensional challenges that include regulatory, medical ethical, socio-cultural, and operational aspects. From the regulatory aspect, harmonization between national provisions and implementation at the regional level as well as effective inter-agency coordination are required. The medical ethics aspect includes the application of bioethical principles such as autonomy, beneficence, non-maleficence, and justice in every stage of transplantation. From the socio-cultural aspect, there are still stigmas and misunderstandings about organ donation that affect public participation. Meanwhile, from the operational aspect, limitations in health facilities and competent medical personnel are obstacles in providing quality transplantation services.

Previous research conducted by Michelle Angelika (2021) showed that the regulation of human organ transplantation from the perspective of Indonesian positive law has provided a strong foundation, although it still requires refinement in the technical aspects of its implementation. Another study by Nurrahmah, Evanadya Izza and Yovita Arie Mangesti (2025) emphasized the importance of equitable organ transplantation regulations to prevent the commercialization of human organs. However, these studies have not specifically analyzed the implementation of Law Number 17 of 2023 in the context of legal protection for living kidney transplant donors.

The phenomenon of organ trafficking cases that still occur, such as the Cambodian kidney trafficking network uncovered in 2023, shows that the legal protection system still has gaps that can be exploited. This case involved organized organ trafficking practices that exploited the economic conditions of vulnerable communities. This situation raises critical questions about the effectiveness of oversight and law enforcement in the organ transplantation system in Indonesia.

The urgency of this research is based on the need for a comprehensive evaluation of the effectiveness of Law Number 17 of 2023 in providing legal protection for living donors. This research will provide an academic contribution in the form of a normative-juridical analysis of the implementation of kidney transplantation regulations, while also providing practical recommendations for improving a more effective and equitable legal protection system.

The objectives of this research are to analyze the legal framework for the protection of living donors in kidney transplantation based on Law Number 17 of 2023 concerning Health and identify the realization of the principle of legal certainty in agreements for kidney transplantation from living donors. This research is expected to provide input for policymakers, health law practitioners, medical personnel, and other stakeholders in developing a safe, ethical, and equitable organ transplantation system.

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RESEARCH METHOD

This research uses a normative legal research method (doctrinal legal research), also known as a juridical-normative approach. Normative legal research aims to analyze applicable legal norms (das sollen) related to the legal protection of living donors in kidney transplantation through an in-depth study of primary, secondary, and tertiary legal sources.

Primary legal sources in this research include: The 1945 Constitution of the Republic of Indonesia, specifically Article 27 paragraph (2), Article 28D paragraph (2), Article 28H paragraph (1), and Article 34 paragraph (3); Law Number 17 of 2023 concerning Health, specifically Article 2, Article 3, Article 4, and Articles 263 to 267 as well as Article 475; Government Regulation Number 53 of 2021 concerning Organ and/or Body Tissue Transplantation; Government Regulation Number 28 of 2024 concerning Implementing Regulations of Law Number 17 of 2023 concerning Health; and other implementing regulations relevant to organ transplantation.

Secondary legal sources include textbooks on health law, national and international scientific journals, results of previous research on organ transplantation, medical bioethics literature, reports and official publications from the Ministry of Health, the Indonesian Nephrology Association, the Indonesian Medical Association, the National Transplantation Committee and the Hospital Accreditation Committee. Tertiary legal sources include legal dictionaries, medical dictionaries, health law encyclopedias and relevant mass media articles on organ transplantation issues.

This research method is qualitative-descriptive-analytical with the aim of obtaining a comprehensive, analytical, and in-depth understanding of the implementation of regulations on kidney transplantation from living donors. This approach was chosen to provide a holistic understanding of the phenomenon of legal norm application, identify gaps between regulations and field practices, and formulate applicable recommendations.

Data collection techniques were carried out through library research which included: inventory of applicable legislation; classification of legal materials based on hierarchy and relevance; systematization of legal materials within a structured analytical framework; collection of bioethics and health law literature; and documentation of legal cases related to organ transplantation that have occurred in Indonesia.

Data analysis was carried out through several systematic stages. First, the description stage which comprehensively outlines the applicable legal provisions. Second, the interpretation stage which interprets the meaning and scope of legal provisions using grammatical, systematic, historical, and teleological methods of interpretation. Third, the evaluation stage which assesses the effectiveness of the implementation of legal provisions in the field by identifying the conformity between das sollen (the law as it should be) and das sein (the law in reality). Fourth, the comparison stage which compares organ transplantation regulations in Indonesia with international best practices. Fifth, the synthesis stage which formulates conclusions and recommendations based on the analysis results. Data validity was ensured through several mechanisms: use of official and trusted data sources from government institutions and professional organizations; source triangulation to verify information from

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various perspectives; use of the latest data and regulations relevant to developments in health law; and consistency in the application of analysis methods.

The entire research process was directed at answering the problem formulation regarding the legal framework for the protection of living donors, the realization of the principle of legal certainty, the implementation of bioethical principles, challenges in implementation, and recommendations for increasing the effectiveness of legal protection for living donors in kidney transplantation in Indonesia.

RESULTS AND DISCUSSION

Legal Framework for the Protection of Living Donors in Kidney Transplantation

The constitutional foundation in the context of legal protection for living donors in kidney transplantation has a strong constitutional basis in the 1945 Constitution of the Republic of Indonesia. Article 28H paragraph (1) of the 1945 Constitution guarantees that "every person has the right to live in physical and spiritual prosperity, to have a place to live, to have a good and healthy living environment and the right to obtain health services". This provision provides a constitutional basis that every citizen, both as a donor and a recipient, has a fundamental right to quality health services.

Article 27 paragraph (2) of the 1945 Constitution mandates that "every citizen shall have the right to work and to a decent living for humanity." In the context of kidney transplantation, this provision guarantees that donors must not experience discrimination in their social and economic life post-donation. Article 28D paragraph (2) affirms that "every person has the right to work and to receive fair and proper remuneration and treatment in employment." Article 34 paragraph (3) of the 1945 Constitution mandates that the state is responsible for organizing a social security system for all people and empowering the weak and incapable in accordance with human dignity, which includes protection for living donors who experience health complications due to organ donation.

National Regulations contained in Law Number 17 of 2023 concerning Health are the main regulations governing organ transplantation in Indonesia. Article 263 defines transplantation as "a medical action performed by moving organs and/or body tissues from one place to another in the same body or from one body to another to replace organs and/or body tissues that are not functioning properly".

Article 264 of Law Number 17 of 2023 establishes the basic principles of transplantation that must be complied with:

1. Transplantation is performed only for humanitarian purposes and not for commercial purposes
2. Carried out in accordance with religious norms and morality
3. Based on the consent of the donor or their family and the consent of the recipient or their family
4. Performed by health workers who have the expertise and authority to do so.

Article 265 of Law Number 17 of 2023 regulates special requirements for living donors which are crucial in providing legal protection:

1. Living donors must be adults and physically and mentally healthy based on medical indications

2. Receive complete explanation regarding the possible consequences of organ and/or body tissue removal for their health
3. Provide written consent
4. Not under pressure from any party
5. Do not receive any form of remuneration.

The prohibition of organ commercialization is strictly regulated in Article 267 of Law Number 17 of 2023 which prohibits:

1. Trading in organs and/or body tissues
2. Advertising the need or availability of organs
3. Acting as an intermediary in the sale and purchase of organs for remuneration

Violations of this prohibition are subject to criminal sanctions as regulated in Article 475 with a maximum prison sentence of 10 years and/or a maximum fine of Rp1,000,000,000.00 (one billion rupiah). These severe sanctions demonstrate the state's seriousness in protecting donors from exploitation and organ trafficking.

Principles of Health Service Implementation

Article 2 of Law Number 17 of 2023 establishes the principles of health service implementation which form the foundation for legal protection for living donors: The Principle of Humanity (letter a) requires that the decision to donate organs must be truly voluntary, without coercion, and carried out with full respect for the human dignity of the donor. The implementation of this principle includes protection of the donor's human rights, protection from exploitation, and assurance that the transplantation procedure is carried out with regard to the donor's physical, mental, and social well-being. The Principle of Protection and Safety (letter g) guarantees the safety of the donor through various mechanisms starting from a comprehensive pre-donation medical evaluation stage, safe and standardized surgical protocols, strict post-operative monitoring systems, to guarantees of access to long-term health services without discrimination. The Principle of Respect for Rights and Obligations (letter h) regulates the balance between the donor's right to donate an organ and the right to receive adequate protection. Donors have the right to receive complete information, the right to give consent freely, the right to receive quality health services, and the right to withdraw consent before the procedure is performed.

The Principles of Justice and Non-Discrimination (letters i and j) require that the entire transplantation process be carried out fairly, transparently and without harming either party. Living donors must not experience any form of discrimination, either in access to health services, medical treatment, or in their social life. The Principle of Legal Certainty (letter s) provides a guarantee that the rights of donors will be protected through clear regulations, transparent procedures, effective law enforcement mechanisms, standardization of transplantation procedures, clarity of the rights and obligations of all parties, a comprehensive documentation system, and a fair resolution mechanism.

Implementing Regulations

Government Regulation Number 53 of 2021 concerning Organ and/or Body Tissue Transplantation is an implementing regulation that details the provisions for organ

transplantation. This PP affirms that organ and/or body tissue transplantation is performed only for humanitarian purposes and is prohibited from being commercialized. The requirements for living donors are regulated in detail, including:

1. Minimum age of 18 years proven by ID card, family card, and/or birth certificate
2. Prime health condition based on examination by a multidisciplinary medical team
3. Existence of a genetic, emotional, or social relationship with the recipient
4. Free from any form of pressure
5. Body mass index (BMI) less than 35
6. Not suffering from diabetes, uncontrolled hypertension, heart disease, or kidney disorders

The informed consent procedure is a fundamental element regulated in Government Regulation Number 53 of 2021, where the donor must make a written statement about their willingness to donate their organ voluntarily without requesting wages, gifts, payments, or remuneration in any form. This consent must be given after the donor receives complete, accurate, and understandable information regarding all aspects of the transplantation procedure.

Implementation of Bioethical Principles in Kidney Transplantation Regulations

1. Principle of Autonomy (Respect for Autonomy)

   The principle of autonomy in kidney transplantation from living donors emphasizes fundamental respect for the individual's capacity to make independent decisions regarding medical actions to be performed on their body. The implementation of this principle includes three important components integrated into Indonesian regulations.

   First, Comprehensive Informed Consent. The donor must receive complete and accurate information regarding all aspects of the transplantation procedure, including the surgical procedure and techniques to be used, short-term risks (surgical complications, infection, bleeding), long-term risks (kidney function, hypertension, proteinuria), transplantation success rate and recipient prognosis, alternative treatments for the recipient, psychological and social impacts of donation, and costs and financing of the procedure.

   Second, Own Will and Freedom from Coercion. The decision to become a donor must be truly voluntary and free from various forms of pressure. Regulations mandate an independent evaluation by a psychologist or psychiatrist to ensure there is no economic, social, or psychological pressure. The donor must be evaluated from the prospective recipient to avoid conflicts of interest.

   Third, Decision-Making Capacity. The donor must have adequate cognitive and emotional capacity to understand the information provided, rationally assess risks and benefits, make decisions consistent with personal values and beliefs, and communicate their decision clearly.

   To provide sufficient time for the donor to consider their decision, regulations set a minimum cooling-off period of 30 days between the initial provision of information and the performance of the transplantation action. During this period, the donor can access additional counseling, consult with independent parties, and has the absolute right to cancel their consent without needing to provide a reason and without any negative consequences.

2. Principle of Beneficence

   The principle of beneficence has a complex application in kidney transplantation as it involves two individuals with different health statuses. This principle must cover three main

aspects. First, maximization of benefits for the recipient. Kidney transplantation provides significant benefits for the recipient, including a dramatic improvement in quality of life, longer life expectancy compared to dialysis, freedom from dependence on dialysis machines, and increased productivity and social participation. Second, minimization of risks for the donor. Regulations mandate very strict medical evaluations to ensure that risks to the donor are minimized as much as possible. This includes comprehensive kidney function tests to ensure the remaining kidney function is sufficiently good, screening for risk factors for future kidney disease, evaluation of cardiovascular conditions, and psychological examinations to assess mental readiness. Third, Risk-Benefit Ratio Evaluation. Each transplantation case must be evaluated individually by considering the specific conditions of the donor and recipient, the probability of transplantation success, potential complications, and available alternative treatments.

3. Principle of Non-Maleficence

   The principle of non-maleficence or "primum non nocere" (first, do no harm) has a unique application in kidney transplantation given that this procedure inherently involves invasive action on a healthy individual. The implementation of this principle includes several important strategies, namely:

   1) Minimization of Operative Risks: Use of minimally invasive surgical techniques such as laparoscopy or robot-assisted surgery to reduce operative trauma, safe anesthesia protocols tailored to the donor's condition, and a highly experienced surgical team in kidney transplantation.
   2) Strict Evaluation of Donor Health Conditions: Complete laboratory examinations for kidney, liver, and other vital organ functions, radiological imaging for kidney anatomy and blood vessels, histopathological evaluation through kidney biopsy if necessary, and screening for infectious diseases and malignancies.
   3) Long-Term Monitoring: Regulations mandate systematic and continuous monitoring of the donor's health post-transplantation, including periodic kidney function checks at least every 6 months in the first year and annually thereafter, blood pressure monitoring and early detection of hypertension, proteinuria checks as an indicator of kidney damage, and priority access to nephrology services if needed.

4. Principle of Justice

   The principle of justice in kidney transplantation relates to the equitable distribution of benefits and burdens within the health service system. The implementation of the principle of justice includes several important dimensions.

   1) Impartial Access: All citizens in need of a kidney transplant must have equal access without discrimination. A fair financing system through national health insurance must be available, equitable health infrastructure across various regions of Indonesia and public education programs to increase awareness about organ donation.
   2) Objective Selection Criteria: Determination of recipient priority must be based on objective medical factors such as medical urgency, level of organ compatibility, waiting time, and prognosis of success, not based on financial ability or social status.
   3) Special Protection for Vulnerable Groups: Regulations provide extra protection for groups vulnerable to exploitation, including communities with weak economic conditions who are vulnerable to organ trafficking, groups with low education levels

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who may not understand the risks, and communities in remote areas with limited access to information and health services.

Realization of the Principle of Legal Certainty in Kidney Transplantation Agreements
Normative Regulatory Aspect

Legal certainty in kidney transplantation is realized through a clear and systematic hierarchy of legislation. This hierarchical structure starts from the constitutional foundation of the 1945 Constitution, then operationalized in Law Number 17 of 2023 concerning Health, and further elaborated in Government Regulation Number 53 of 2021 concerning Organ Transplantation. This clear hierarchy provides predictability for all parties regarding the rights, obligations, and legal consequences of organ transplantation actions.

Regulatory clarity includes firm definitions of key terms such as transplantation, living donor, recipient, and organ commercialization. Specific regulations regarding procedures, requirements, and oversight mechanisms provide certainty for medical practitioners and prospective donors about what is expected and what is prohibited in the transplantation process.

Procedural Aspect: Informed Consent Mechanism

Legal certainty is manifested in a strict and structured informed consent mechanism. This process is not merely an administrative formality, but rather a legal instrument that guarantees the donor's decision is made with full awareness and understanding. The Structured Informed Consent Stages are:

1) Initial Provision of Information: The medical team provides comprehensive information about the transplantation procedure in easily understandable language, using visual media and written materials that the prospective donor can take home.
2) Multidisciplinary Counseling: The prospective donor meets with various experts including urology specialists, nephrology specialists, psychologists or psychiatrists, transplant counselors, and medical ethics experts. Each profession provides a different perspective to ensure the donor understands all aspects of donation.
3) Independent Evaluation: The team evaluating the donor must be separate and independent from the team handling the recipient to avoid conflicts of interest and ensure that the donor's interests are the top priority.
4) Cooling-off Period: A minimum waiting period of 30 days provides time for the prospective donor to reflect on their decision, discuss with family, seek additional information, and consult with other parties without pressure.
5) Written Consent: After all stages are completed, the donor signs a consent form that includes a statement of having received and understood all information, stating willingness voluntarily without pressure, stating not receiving any remuneration, and understanding the right to cancel consent at any time before the surgery.

Material Requirements Aspect

Legal certainty is realized through the establishment of firm and measurable criteria for living donors. These requirements provide objective standards that must be met, thereby reducing subjectivity and potential misuse. Administrative Requirements include:

1) Minimum age of 18 years proven by official documents (ID card, family card, birth certificate)
2) Clear and verifiable identity
3) Letter of relationship with the recipient (to prove genetic, emotional, or social relationship)

Medical Requirements include:

1) Prime general health without significant chronic diseases
2) Normal kidney function with Glomerular Filtration Rate (GFR) above 80 mL/min
3) Body Mass Index (BMI) less than 35
4) Not suffering from diabetes mellitus, uncontrolled hypertension, significant heart disease, or kidney disease
5) Normal laboratory results for liver function, lipid profile, and other health parameters
6) No history of malignancy or active infectious diseases

Psychological Requirements include:

1) Adequate mental capacity to understand the procedure and risks
2) No uncontrolled major psychiatric disorders
3) Pure motivation to donate organs without expectation of remuneration
4) Adequate social support from family and environment.

These clear criteria provide certainty for prospective donors about their eligibility and for medical teams about the evaluation standards that must be applied.

Prohibition of Commercialization and Legal Sanctions

Legal certainty in protecting donors from exploitation is realized through a firm prohibition of organ commercialization accompanied by severe criminal sanctions. Article 267 of Law Number 17 of 2023 explicitly prohibits:

1) Trading in human organs and/or body tissues
2) Advertising the need or availability of organs for commercial purposes
3) Acting as an intermediary in the sale and purchase of organs by receiving remuneration.

Violations of this prohibition are subject to criminal sanctions as regulated in Article 475 with a maximum prison sentence of 10 years and/or a maximum fine of Rp1,000,000,000.00. These significant sanctions provide a deterrent effect and demonstrate the state's seriousness in protecting donors from organ trafficking.

The Indonesian Medical Association firmly affirms that the sale and purchase of organs, including kidneys, is an illegal act and violates the medical code of ethics. Donors are strictly prohibited from receiving money, gifts, or any form of remuneration for the organ donated, because transplantation must be performed solely for humanitarian purposes and not for economic gain.

National Registration and Monitoring System

Legal certainty is strengthened through an integrated transplantation registration and monitoring system from the hospital to the national level. Every prospective donor and recipient must be registered in the national health information system managed by the Ministry of Health.

The Registration Process includes:

1) Recording of complete identity data of the donor and recipient

2) Documentation of comprehensive medical evaluation results
3) Recording of the informed consent process
4) Documentation of the relationship between donor and recipient
5) Tracking of all transplantation stages from evaluation to long-term follow-up.

The National Organ Transplantation Database functions as an information center that includes:

1) Waiting list of recipients in need of transplantation
2) Data on living donors and deceased donors
3) Organ compatibility matching process
4) Transplantation results and outcomes
5) Long-term follow-up data of donors and recipients.

This system enables fair and transparent organ allocation based on medical priority, organ compatibility and the first come first served principle for cases with the same level of urgency. Transparency in this system reduces the potential for discrimination in access to transplantation.

Facility Certification and Standardization

Legal certainty regarding service quality is realized through strict requirements for hospitals conducting transplantation. Hospitals must have:

Special Accreditation, includes:

1) Certification from the Ministry of Health to perform organ transplantation
2) Accreditation from the Hospital Accreditation Committee (KARS) with special standards for transplantation services
3) International certification such as Joint Commission International (JCI) for hospitals wanting to achieve global standards.

Adequate Facilities:

1) Special operating room with advanced equipment for transplant surgery
2) Intensive care unit (ICU) with strict monitoring capacity
3) Complete laboratory for organ compatibility examination and post-transplantation monitoring
4) Blood bank with adequate availability of blood products
5) Radiology and medical imaging facilities for pre and post-operative evaluation

Competent Medical Personnel:

1) Urology or surgery specialists certified in kidney transplantation
2) Nephrology specialists with experience in managing transplant patients
3) Anesthesiology specialists with special expertise in transplant anesthesia
4) Specialist nurses trained in the care of transplant patients
5) Certified transplant coordinator team

Medical personnel qualifications must be periodically updated through Continuing Medical Education (CME) programs and competency re-certification to keep knowledge and skills up-to-date.

Tiered Oversight Mechanism

Legal certainty in implementation is strengthened through an integrated and tiered oversight system, Hospital Level includes:

1) Medical Committee conducting internal audits of transplantation procedures
2) Ethics Committee evaluating ethical aspects of each transplantation case
3) Hospital Transplantation Committee coordinating the entire transplantation process

Regional Level includes:

1) Provincial Health Office conducting supervision and monitoring of hospitals conducting transplantation
2) Periodic evaluation of hospital compliance with standards and protocols
3) Handling complaints and reports of alleged violations

National Level includes:

1) Directorate General of Health Services, Ministry of Health, conducting national coordination and oversight
2) National Transplantation Committee monitoring the development of transplantation programs throughout Indonesia
3) Policy evaluation and system improvement recommendations.

The mandatory transplantation reporting system requires hospitals to report each transplantation case within a maximum of 24 hours after the action is performed, including donor data, recipient data, the involved medical team, and initial post-action results. This reporting transparency enables national evaluation of transplantation program quality and identification of areas requiring improvement.

Administrative and Criminal Sanctions

Legal certainty includes clear and proportional sanction mechanisms for violations. Administrative Sanctions can include:

1) Written reprimand for minor violations
2) Temporary suspension of transplantation activities for moderate violations
3) Revocation of operational permit for serious violations
4) Closure of transplantation facilities for very serious or repeated violations

Administrative sanctions are imposed through a due process that involves thorough investigation, clarification with the alleged violator, opportunity for defense, and a decision that can be appealed.

Criminal Sanctions as regulated in Article 475 of Law Number 17 of 2023 are imposed for:

1) Trafficking of human organs
2) Forgery of documents related to transplantation
3) Coercion or fraud against prospective donors
4) Illegal transplantation practices without permits and established standards

Law enforcement is carried out through cooperation between health authorities (Ministry of Health), police, prosecutors, and other law enforcement institutions to ensure the effectiveness of imposed sanctions and provide a deterrent effect.

Challenges in Implementing Legal Protection

Regulatory Challenges

Although the legal framework is comprehensive, its implementation still faces several significant regulatory challenges. The organ transplantation regulatory system, which involves various regulations from the law level to technical regulations, can cause confusion for field implementers. Not all health workers and hospital administrators have the same understanding of the interpretation and application of regulations. Organ transplantation involves various

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institutions such as the Ministry of Health, hospitals, regional health offices, professional organizations (IDI, Pernefri) and certification bodies. Ineffective coordination can lead to inconsistencies in the implementation of standards and oversight. Harmonization of Regional Regulations: not all regions have Regional Regulations (Perda) or technical regulations that are aligned with national regulations. This gap can lead to varying protection standards in different regions of Indonesia. Regulatory Updates: Medical technology and transplantation practices develop very rapidly, but regulations are often slow to adapt. This gap can create legal loopholes or, conversely, hinder beneficial medical innovation.

Operational Challenges

Limitations of Human Resources: Not all hospitals have competent and experienced medical personnel in kidney transplantation. The number of urology and nephrology specialists with transplantation certification is still limited, especially outside major cities like Jakarta, Surabaya, and Bandung. Facility Limitations: Only a small number of hospitals in Indonesia have complete facilities to perform kidney transplantation according to international standards. These facilities are generally concentrated in major cities, so access for communities in remote areas is very limited. Not Fully Integrated Information System: Although regulations mandate a national registration and monitoring system, the implementation of an integrated information system still faces technical and administrative obstacles. Many hospitals still use manual systems or digital systems that are not compatible with the national platform. Budget Limitations: Donor protection programs require significant investment in terms of human resources, facilities, and systems. Limitations in health budgets, especially in regions become a constraint in providing quality transplantation services.

Social and Cultural Challenges

Social Stigma: In some regions, organ donation is still considered taboo or contrary to certain cultural and religious values. This stigma can cause donors to experience undue discrimination or social pressure from their surroundings. Inequality of Access to Information: Communities in remote areas or with low education levels often do not have adequate access to information about organ transplantation and their rights as donors. This information gap can lead to uninformed decisions or even exploitation. Economic Exploitation: Cases of organ trafficking that occur show that communities with weak economic conditions are vulnerable to exploitation. Although regulations prohibit organ commercialization, covert practices still occur by exploiting difficult economic conditions. Low Legal Awareness: Not all prospective donors understand their legal rights, including the right to refuse, the right to receive complete information, and the right to receive long-term health protection. This low legal awareness can make donors not demand their rights when violations occur.

Law Enforcement Challenges

Organ Trafficking Cases: Cases of kidney trafficking networks uncovered, such as the Cambodia case in 2023, show that although regulations exist, oversight and law enforcement still have gaps that can be exploited. Organized organ trafficking practices that exploit the economic conditions of vulnerable communities indicate the need to strengthen the oversight system. Effectiveness of Sanctions: although the threatened criminal sanctions are quite severe,

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the effectiveness of sanction enforcement is still questionable. Some violation cases are undetected or not processed to court, so the deterrent effect is not optimal. Proving Violations: Proving the existence of organ commercialization or pressure on donors is often difficult because transactions are conducted secretly and covertly. A more sophisticated investigation system and better agency cooperation are needed.

Recommendations for Increasing the Effectiveness of Legal Protection

Strengthening the Regulatory Framework through Vertical and Horizontal Regulatory Harmonization. Systematic efforts are needed to align regulations at the central and regional levels as well as across sectors. The Ministry of Health needs to facilitate the preparation of regional regulations that are aligned with Law Number 17 of 2023 and PP Number 53 of 2021, as well as conduct synchronization with other regulations such as health insurance regulations and hospital licensing.

Simplification of Procedures: Transplantation procedures need to be simplified without compromising donor safety and protection standards. This can be done by developing clear and practical standard operating procedures (SOPs), using digital technology to facilitate administration, and eliminating unnecessary requirement duplications.

Strengthening Sanction Mechanisms: The sanction system needs to be strengthened with clearer and more proportional gradations, a reward system for hospitals and medical personnel with good donor protection performance (reward and punishment), and the implementation of a blacklist mechanism for serious violators that is publicly accessible.

CONCLUSION

This research shows that Law Number 17 of 2023 concerning Health and its implementing regulations have provided a comprehensive legal framework for the protection of living donors in kidney transplantation in Indonesia. This regulation is built on a strong constitutional foundation and integrates fundamental bioethical principles that include autonomy, beneficence, non-maleficence, and justice in every aspect of its regulation.

From the normative aspect, the legal framework for kidney transplantation has regulated in detail the requirements for donors, informed consent procedures, prohibition of organ commercialization, registration and monitoring systems, as well as oversight and sanction mechanisms. The principles of health service implementation listed in Article 2 of Law Number 17 of 2023, specifically the principles of humanity, protection and safety, respect for rights, justice, non-discrimination and legal certainty have provided a foundation for the protection of living donors.

The realization of the principle of legal certainty is manifested in various dimensions, including a clear regulatory hierarchy, a structured informed consent procedure, firm material requirements, prohibition of commercialization with severe sanctions, an integrated national registration and monitoring system, standardization and certification of health facilities, a tiered oversight mechanism, and proportional administrative and criminal sanctions. This entire mechanism provides legal guarantees that are predictable, transparent, and reliable for living donors.

The implementation of bioethical principles in kidney transplantation regulations demonstrates Indonesia's commitment to adopting international medical ethics standards. The

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principle of autonomy is realized through a comprehensive informed consent mechanism and a cooling-off period that provides adequate consideration time. The principles of beneficence and non-maleficence are implemented through strict medical evaluations, the use of minimally invasive surgical techniques, and a long-term monitoring system. The principle of justice is practiced through an objective organ allocation system and special protection for vulnerable groups.

However, this research also identifies various challenges in the implementation of legal protection. Regulatory challenges include regulatory complexity, limitations in inter-agency coordination, gaps in regional regulatory harmonization, and slow regulatory updates following developments in medical technology. Operational challenges include limitations in human resources, uneven health facilities, a not fully integrated information system, and budget limitations. Social and cultural challenges include social stigma against organ donation, inequality of access to information, economic exploitation of vulnerable groups, and low public legal awareness. Law enforcement challenges are indicated by still occurring organ trafficking cases, suboptimal effectiveness of sanctions, and difficulties in proving violations.

The implementation of these recommendations requires strong political commitment from the government, adequate resource allocation, good coordination among stakeholders, and active community participation. With optimal implementation, Law Number 17 of 2023 concerning Health can become an effective instrument in realizing legal protection for living donors that is comprehensive, fair, and sustainable.

This research provides an academic contribution in the form of an in-depth normative-juridical analysis of the implementation of Law Number 17 of 2023 in the context of kidney transplantation from living donors, while also providing practical recommendations for increasing the effectiveness of the legal protection system. The findings of this research can be a reference for policymakers, health law practitioners, medical personnel, and other health system actors in developing a safer, more ethical, and equitable organ transplantation system. With a strong legal protection system and effective implementation, kidney transplantation from living donors can become a safe and sustainable therapy alternative for end-stage renal disease patients in Indonesia, while still guaranteeing optimal protection for donors who have provided a humanitarian contribution.

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