Legal Protection for Patients Participating in Health Insurance Administering Agencies with Heart Disease with Medication Restrictions in Outpatient Services in Hospitals

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Abstract

Health is a human right that must be realized in accordance with Pancasila and the 1945 Constitution. BPJS patients have the right to get good health services and medicines according to their diseases, including heart disease. The administration of drugs in the National Health Insurance (JKN) program must be in accordance with the National Formulary (Fornas). There are rules regarding drug restrictions in Fornas that cause problems in outpatient services for BPJS patients with heart disease. The purpose of this research is to analyze the legal protection of patients and the hospital's responsibility for drug restrictions. Research Methods: The type used in this study is normative juridical with a statute approach and a conceptual approach. Collection and processing of legal materials using document studies or library materials with added literature, journals and expert opinions related to legal issues and then read, studied and analyzed to arrive at a conclusion. Results: Legal protection for BPJS patients with heart disease is contained in the 1945 Constitution and the Law on Health in 2023. The hospital is also responsible for BPJS patients to get medicines according to medical examination. Conclusion: BPJS patients with heart disease have legal protection to get optimal therapy and the hospital is responsible for administering restricted heart drugs so that patients get therapy according to the guidelines.

Keywords: Legal Protection, Health Insurance Administering Agencies, Heart Disease, Drug Restrictions, Hospitals
INTRODUCTION

Health, education and the economy are parameters that are interconnected and cannot be separated from one another.\(^1\) Health development as an element of general welfare is the government's responsibility which must be realized in accordance with the ideals of the Indonesian nation contained in the preamble to the 1945 Constitution (hereinafter referred to as the 1945 Constitution), namely to protect the entire Indonesian nation and all of Indonesia's blood and to promote general welfare, making the nation's life intelligent and participating in implementing world order based on freedom, eternal peace and social justice.\(^2\)

The government has established the national health insurance program (hereinafter referred to as JKN) as one of the social security programs in the social security system. This is stated in Law Number 40 of 2004 concerning the National Social Security System (hereinafter referred to as the SJSN Law). As the implementer of JKN, the government through the Social Security Administering Agency (hereinafter referred to as BPJS) Health for administering the JKN program and BPJS Employment for administering work accident insurance, old age insurance, pension insurance and death insurance programs. This is regulated in Law Number 24 of 2011 concerning Social Security Administering Bodies (hereinafter referred to as the BPJS Law).

The right to obtain good health services also includes obtaining health services for heart disease. The results of the latest basic health research by the Ministry of Health show that the prevalence of cardiovascular disease continues to increase, such as hypertension increasing from 25.8% in 2013 to 34.1% in 2018, while coronary heart disease was 1.5% in 2018.\(^3\) Heart disease is one of the highest causes of death in Indonesia and even the world. Treatment for heart disease requires a long time, special treatment from a heart specialist and of course a lot of money. In several discussions and interviews, the Minister of Health also highlighted heart disease. In fact, heart disease is one of the highest costs that the government must bear.

Treatments of heart disease is not only when the patient is admitted to the inpatient setting but also during control in the outpatient service. Because most heart diseases require a long period of routine control and treatment, even treatment is carried out for life. To reduce and make financing more effective, special planning and strategies are needed by the government.

In implementing the JKN program, the government must apply the principles of quality control and cost control, including for the use and financing of medicines. The government's considerations in selecting drugs pay attention to quality, cost effectiveness and their use must be rational. Based on the mandate of the SJSN Law that the government makes a list and prices of medicines that can be guaranteed by BPJS Health, this gave birth to the National Formulary (hereinafter referred to as Fornas) and a mechanism for purchasing medicines through E-catalogue.\(^4\)

Fornas is a list of medicines compiled by a national committee appointed by the Minister of Health, based on the latest scientific evidence, useful, safe and affordable prices provided and used as a reference for the use of medicines in JKN. Drug management must pay attention to quality control and cost control. Drug use is also regulated at each level of health

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\(^4\) Ministry of Health of the Republic of Indonesia, Main Results of Riskesdas 2018, Ministry of Health, Health Research and Development Agency, 2018, p. 79-83

\(^5\) Syahdu Winda, National Formulary (FORNAS) and e-Catalogue Drugs as Efforts to Prevent Corruption in National Health Insurance (JKN) Drug Administration, Integrity, No.2 Volume 4, 2018, p. 181.
facilities to avoid irrational drug use. However, in the implementation of Fornas, problems were still found which resulted in it not being able to achieve its objectives optimally.\textsuperscript{6}

There are various provisions for the use of drugs regulated in Fornas, such as indications, restriction provisions, maximum prescriptions and health facility level provisions. This rule is explained in Minister of Health Regulation Number 54 of 2018 concerning the Preparation and Application of the National Formulary in the Implementation of the Health Insurance Program. The Minister of Health Regulation states that restrictions on drug use are limitations related to indications, contraindications, quantity and duration of drug use for each case/episode, the authority of the prescriber, based on the results of specific required supporting examinations, as well as other conditions that must be met in order to Medication can be prescribed properly and correctly. This rule also applies to the treatment of heart disease. Evaluation and changes to drug restrictions cannot be done immediately. The process takes a long and long time until it is determined by the minister.

Based on the problem formulation presented, the aim of the research is to analyze the form of legal protection for BPJS participant patients with heart disease who experience drug restrictions in outpatient services at hospitals and to analyze the hospital's responsibilities in the presence of drug restrictions for heart patients in hospitals.

\textbf{RESEARCH METHODS}

This type of research is normative juridical, namely research that focuses on examining the application of norms or rules in positive law.\textsuperscript{7} Legal research (legal research, rechtsonderzoek) is a scientific process to find solutions to legal issues that arise with the aim of providing prescriptions about what should be done regarding the legal issues that arise. The approaches used in this research are the statutory approach and the conceptual approach.\textsuperscript{8} The legislative approach is an approach that uses legislation and regulations. Products that are beschikking/decree, namely a decision issued by an administrative official that is concrete and specific in nature, such as presidential decrees, ministerial decrees, regent's decrees, and decisions of certain bodies, cannot be used in a legislative approach. The Conceptual Approach is used to find solutions to legal issues faced where the rules that guide decision making are not yet perfect, so that legal views, legal doctrine and relevant legal principles are needed in this research.\textsuperscript{9}

\textbf{RESULT AND DISCUSSION}

\textbf{Legal Protection for BPJS Patients with Heart Disease Who Experience Drug Restrictions in Hospitals}

Legal protection consists of two words, namely protection and law. Protection is a series of activities to guarantee and protect a person, while law is the totality of regulations that must be obeyed by everyone and those who violate them are subject to sanctions. Legal protection is an activity to guarantee someone which is carried out through legal procedures or based on law.\textsuperscript{10} In general, legal protection is a guarantee given by the state to all parties to be able to exercise the legal rights and interests they have in their capacity as legal subjects.\textsuperscript{11}

\textsuperscript{6}Ibid.
\textsuperscript{8}Marzuki Peter Mahmud, Legal Research, Kencana Prenada Media Group, Jakarta, 2005, p. 59-60
\textsuperscript{9}Ibid.
\textsuperscript{10}M Nurdin, Legal Protection for Patients Victims of Medical Malpractice, Samudra Perempuan Law Journal, No. 1 Volume 10, 2015, p. 93-94.
\textsuperscript{11}Andriyadi, Legal Protection of the Rights of BPJS Health Patients at Eka Hospital Pekanbaru, Thesis, Master of Law Study Program, Islamic University of Riau, Pekanbaru, 2022, p. 55.
Legal protection is all efforts to protect and fulfill the rights and sense of security for witnesses and/or patient victims. Forms of legal protection can be provided in the form of providing restitution, compensation, medical services and legal assistance. The basis for legal protection in Indonesia, as written in the Preamble to the 1945 Constitution, is: "to protect the entire Indonesian nation and all of Indonesia's blood."

According to Satjipto Rahardjo, the presence of law in society has an important role, including integrating and coordinating interests that could collide with each other by law, by being integrated in such a way that these collisions can be reduced to a minimum. Organizing these interests is carried out by limiting and protecting these interests. The law protects a person by allocating force to him to act in that interest. According to Philipus Hadjon, legal protection takes two forms: first, preventive legal protection, which means that the people are given the opportunity to express their opinions before the government's decision takes a definitive form which aims to prevent disputes from occurring. Second, repressive legal protection which aims to resolve disputes.

Philosophically, the regulations for health services for the community in Indonesia come from Article 34 paragraph (1) of the 1945 Constitution which stipulates that health services are the responsibility of the state, and Article 28H paragraph (1) which stipulates the rights of citizens to obtain health services. This is an embodiment of the principles of just and civilized humanity and the principles of social justice for all Indonesian people. The provision of health services is related to values that uphold the dignity of Indonesian people, while the establishment of the right to receive health services is an embodiment of the principle of social justice which is realized by equality.

Legal protection and health services cover several aspects, including: administrative aspects, criminal aspects and civil aspects. The administrative aspect is related to the type and quality of basic services to ensure patient safety in hospitals. The criminal aspect of protecting the public to obtain public health services is a repressive aspect, namely when malpractice occurs by hospital doctors. In reality, this aspect is often focused on doctors rather than hospitals. In fact, therapeutic transactions are a legal relationship between the hospital and the patient. So the legal action taken by the hospital doctor is due to the authority given by the hospital to the doctor concerned. The last aspect is the civil aspect, this aspect is also related to repressive protection, namely legal protection in the event of loss caused by the doctor's error/negligence. This legal protection includes health services for outpatients who experience heart medication restrictions in hospitals.

In health services, there is a legal relationship between the health service provider and the health recipient. The result of this relationship gives rise to a transaction known as a therapeutic transaction. Based on Law Number 29 of 2004 concerning Medical Practice and Law Number 44 of 2009 concerning Hospitals, therapeutic transactions give rise to rights and obligations between parties where this therapeutic transaction is the basis for granting approval for medical treatment (informed consent). Informed consent is a form of legal protection for patients.

The state is also present to provide legal protection for patients in the form of statutory regulations, namely Law Number 36 of 2009 concerning Health, Law Number 44 of 2009

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12Tri putri Simamora et al., Legal Protection of Patients in Medical Services in General Hospitals, Al' Adl Legal Journal, No. 2 Volume 12, 2020, p. 272-273.
13M Nurdin, Loc. Cit.
14Fauji Salim, Normative Juridical Review of Legal Protection for Patients as Consumers in Malpractice in Hospitals, Lex Renaissance, No.2 Volume 5, 2020, p. 395.
15Ibid., h. 397.
16Ibid., p. 398-399.
17Rielia Darma Bachriani and Putri Kusuma Wardhani, Juridical Study of Legal Protection for Patients Regarding Health Services in Hospitals, Smart Law Journal, No.1 Volume 1, 2022, p. 5.
concerning Hospitals, Law No. 29 of 2004 concerning Medical Practice, Law Number 39 of 1999 concerning Human Rights, the Civil Code and Government Regulations. And the latest is Law Number 17 of 2023 concerning Health.

Legal protection for patients receives clear attention in Law Number 29 of 2004 concerning Medical Practice which explains that health development is aimed at increasing awareness, willingness and ability to live healthily for everyone in order to realize optimal health as an element of general welfare. As intended in the Preamble to the 1945 Constitution. Examples of legal protection in the Medical Practice Law are contained in Articles 27 and 28 which explain about medical and dental education and training carried out in accordance with professional standards, Article 51 concerning the obligations of doctors and dentists in carrying out medical practice, Article 66 concerning complaints from patients who feel disadvantaged by the actions of doctors and dentists, and Article 72 which explains the guidance and supervision of doctors and dentists to improve the quality of health services and provide legal certainty for the public, doctors and dentists.

Law Number 36 of 2009 concerning Health also provides guarantees for patient protection, especially Articles 56 to 58. These three articles explain that patients have the right to accept and reject some or all of the assistance measures that will be given to them after receiving and understanding information regarding these actions in full, has the right to keep his personal health condition confidential and to claim compensation due to negligence of health services. Article 2 of Law Number 44 of 2009 concerning Hospitals guarantees patient protection and safety. This article explains the meaning of the value of patient protection and safety, namely that hospital administration must not only provide health services, but must be able to provide an increase in health status while still paying attention to patient protection and safety.

Legal protection for patients is also guaranteed in Law Number 17 of 2023 concerning Health which has been passed. Chapter II in these regulations is about the rights and obligations in Article 4. Every person has the right to receive safe, quality and affordable health services and to obtain health services that comply with health service standards. Article 189 states the obligation of every hospital to respect and protect the rights of patients. The latest Health Law in Part Three concerning the procurement of medical personnel and health workers in Article 219 also regulates that students who provide health services have an obligation to respect, protect and fulfill the rights of patients. Medical personnel and health workers in carrying out practice are also regulated in Article 274 which requires them to provide health services in accordance with professional standards, professional service standards, standard operational procedures and professional ethics as well as patient health needs. Based on this, heart patients participating in BPJS who experience restrictions on prescribing medication, if the medication is considered by a heart specialist referring to existing therapy guidelines, must still be given to the patient in order to obtain the appropriate and best therapy for their disease.

Legal protection for patients is also regulated in the Civil Code Article 1365 which states "Every act that violates the law and causes loss to another person, requires the person who caused the loss through his fault to compensate for the loss." Based on the sound of this article, the following elements of unlawful acts can be drawn:

1. There is an act that violates the law
2. There are losses
3. There is a mistake
4. There is a causal relationship between the loss and the action

The legal relationship between a doctor and a patient is a legal relationship in the civil sector which in the Civil Code is discussed in Book III concerning engagement. Legal obligations can arise from law or from agreements. What is meant by the parties agreeing in health services is the agreement of the doctor to carry out medical procedures and the consent
of the patient for medical procedures to be carried out on him. So the informed consent given by the patient is a requirement for the agreement to provide medical services to be valid according to law and gives the doctor the right to carry out medical procedures. This is in accordance with Article 1320 of the Civil Code, namely that an agreement is said to be valid if it meets four conditions:

1. They agreed to bind themselves
2. The ability to create an engagement
3. A certain thing
4. A legitimate cause

Specifically regulated in the Regulation of the Minister of Health of the Republic of Indonesia No.290/Menkes/Per/III/ 2008 concerning Approval of Medical Procedures Article 2 paragraph (1) all medical procedures to be carried out on patients must receive approval. In the process of implementing informed consent, the patient gives consent and the doctor provides medical treatment, so that in the relationship between the patient and the doctor, no one will be harmed so that the patient can obtain the rights to obtain proper health.

**Hospital Responsibilities and Obligations in Health Services Related to Collaboration with BPJS**

The relationship between the patient and the hospital is a therapeutic relationship, as a result of this relationship gives rise to rights and obligations for each party. The engagement that occurs between the recipient of health services and the provider of health services is an effort engagement (inspanning verbintenis). As a result of this engagement, there are legal consequences where the hospital is not burdened with the obligation to produce results (in the form of healing) but is only burdened with the obligation to make efforts according to standards (standards of care), namely a level of quality of medical services that reflects the application of knowledge, skills, consideration and proper attention as is done by doctors in general when dealing with similar situations and conditions.

Health services carried out as an effort according to standards with such a level of quality are expected to be able to provide solutions to patient health problems. If in reality these hopes do not come true or even unexpected events arise (adverse events), medical risks, the patient does not recover or dies (terminal bed), then the doctor or hospital does not necessarily have to be blamed or cannot be sued legally for accountability.

Hospital obligations are regulated in Article 29 of Law Number 44 of 2009 concerning Hospitals. Hospital obligations are also stated in more detail in Minister of Health Regulation Number 4 of 2018 concerning Hospital Obligations and Patient Obligations. Every Hospital has the obligation to:

a. provide correct information about Hospital services to the community;

b. provide safe, quality, anti-discriminatory and effective health services by prioritizing the interests of patients in accordance with hospital service standards;

c. provide emergency services to patients according to their service capabilities;

d. play an active role in providing health services during disasters, according to their service capabilities;

e. provide facilities and services for disadvantaged or poor people;

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20 Rossi Suparman, Legal Protection and Hospital Responsibility for Doctors in Medical Disputes, Syiar Hukum Journal of Legal Sciences, No. 2 Volume 17, 2020, p. 189-191
21 Ibid.
f. carry out social functions, among others, by providing service facilities for indigent/poor patients, emergency services without down payment, free ambulances, services for victims of disasters and extraordinary events, or social services for humanitarian missions;
g. create, implement and maintain quality standards for health services in hospitals as a reference in serving patients;
h. maintain medical records;
i. providing adequate public facilities and infrastructure, including prayer facilities, parking, waiting rooms, facilities for the disabled, breastfeeding women, children, the elderly;
j. implementing a referral system;
k. refuse the patient's wishes which are contrary to professional and ethical standards and statutory regulations;
l. provide correct, clear and honest information regarding patient rights and obligations;
m. respect and protect patient rights;
n. implement Hospital ethics;
o. have an accident prevention and disaster management system;
p. implementing government programs in the health sector both regionally and nationally;
q. make a list of medical personnel who practice medicine or dentistry and other health personnel;
r. prepare and implement internal hospital regulations (hospital by laws);
s. protect and provide legal assistance to all Hospital officers in carrying out their duties; And
t. enforce the entire hospital environment as a smoke-free area.

A hospital is one of the public service delivery organizations that has public responsibility for every public service provided in the health sector. The public responsibility of hospitals is regulated in the provisions of Article 15 of Law Number 25 of 2009 concerning Public Services, namely
1. The realization of clear boundaries and relationships regarding the rights, responsibilities, obligations and authority of all parties related to public service providers.
2. The realization of a proper service delivery system in accordance with the general principles of good government and corporations
3. Fulfillment of the implementation of public services in accordance with statutory regulations.
4. The realization of legal protection and certainty for the community in the provision of public services\textsuperscript{22}

Based on Article 46 of Law Number 44 of 2009 concerning Hospitals, it is stated that hospitals have legal responsibility for all losses incurred due to negligence committed by health workers in hospitals. A similar thing is also stated in Law Number 17 of 2023 Article 193 that hospitals are legally responsible for all losses incurred due to negligence committed by hospital health human resources.

Hospitals are one of the providers of health services or more accurately referred to as health facilities. Health services in hospitals and all supporting health facilities such as laboratories, pharmaceutical installations and pharmacies are health services guaranteed by BPJS Health.

\textsuperscript{22}Ariawan Gunadi and Ida Nursida, Juridical Review of Hospital Accountability for Participation in the Health Social Security Administering Agency (BPJS) Program, Legal Era, No.1 Volume 17, 2019, p.37.
All government and regional government hospitals that meet the requirements are required to collaborate with BPJS Health. Meanwhile, private health facilities that have met the requirements can collaborate with BPJS Health.\textsuperscript{23} This is in accordance with Article 36 of Presidential Regulation Number 19 of 2016 concerning the Second Amendment to Presidential Regulation Number 12 of 2013 concerning Health Insurance. Collaboration between hospitals and BPJS is carried out by making a written agreement.

BPJS Health, Hospitals and BPJS Health Participants have a legal relationship relating to their respective rights and obligations. The implementation of relationships between doctors, hospitals and patients is always regulated by certain regulations to create harmony in carrying out the relationship. Such as BPJS Health with its legal basis is Law Number 40 of 2004 concerning the Social Security System and Law Number 24 of 2011 concerning the Social Security Administering Body which has the obligation to guarantee the health of all JKN participants who have joined as BPJS participants. BPJS Health has received its right, namely that participants are required to pay mandatory contributions as social security participants or their contributions are paid by the Government.\textsuperscript{24}

According to Law Number 36 of 2009 concerning Health, hospitals also have obligations, including having minimum qualifications and having permission from the government to provide health services. Hospitals or health facilities are obliged to provide health services according to the provisions and provide service reports according to the agreement. It is the hospital's obligation to provide medicines, medical devices and consumable medical materials according to Fornas to BPJS participant health services. In addition, the Health Law stipulates that health workers must comply with a code of ethics, professional standards, rights of health service users, service standards and operational standards. Apart from obligations, hospitals also have the right to have their claims paid by BPJS in accordance with the health services they provide to national health insurance participants. Claim payment is no later than 15 working days after the complete claim documents are received. Another health facility's right is to obtain information about membership, service procedures, payments and the cooperation process with BPJS.\textsuperscript{25}

All health facilities that collaborate with BPJS Health in Presidential Regulation Number 19 of 2016 are not allowed to charge additional fees to BPJS participating patients as long as the participants use BPJS according to their rights. This is because all costs used during BPJS health services are borne by BPJS according to their rights.

CONCLUSION

Based on the findings in the research, the conclusion of the research results is that the legal consequences for hospitals that employ health workers in anesthesia services who do not comply with competence and regulations can be divided into 3 (three) legal consequences in the form of civil, criminal and administrative sanctions. Based on civil sanctions, hospitals can be sued for compensation by patients due to negligence committed by health workers after it is proven that the anesthetist who distorted the service (malpractice) harmed the patient is a worker who is the hospital's subordinate.

In terms of criminal sanctions, if the hospital is proven to legally have a legal relationship with the anesthetist, the hospital can be subject to a criminal fine as regulated in Article 82 paragraph (2) of the Health Personnel Law, however, if the hospital can prove that it does not have a legal relationship with an anesthetist, the anesthetist may be subject to a fine

\textsuperscript{23}Febri Murtiningtias, H. Zulkarnain Ibrahim, M. Ridwan, Cooperation Agreement Between the Social Security Administering Body and RSUP DR. Mohammad Hoesin in the Implementation of Health Services, Lex Lata, No. 1 Volume 3, 2021, p. 139

\textsuperscript{24}\textit{Ibid.}, h. 141

\textsuperscript{25}\textit{Ibid.}, p. 142-143
as stipulated in Article 86 paragraph (1) of the Health Personnel Law. Meanwhile, in terms of administrative sanctions, hospitals that do not carry out various obligations as regulated in paragraph (1) of the Hospital Law can be subject to administrative sanctions in the form of warnings, written warnings, or fines and revocation of the hospital's license.

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