Informed Consent Procedures in Persons with Mental Disorders: A Juridical Review

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Abstract
No field escapes in the context of law, including, in this case, health, so in the law itself, it is known as health law as a branch of science. Health itself is not only in the physical context but also mental, but what if the person with a mental disorder is physically ill? Of course, it requires a doctor's action consent or informed consent from the person with the mental disorder. In law, proficiency is known as a condition for the validity of an agreement, and people with mental disorders are not included in the clever person. So, in the research article, researchers are interested in analysing and knowing how favourable laws that regulate are related to informed consent in Indonesia and how legal procedures are related to informed consent in laws and regulations in Indonesia for patients with mental disorders. The method that researchers use is the normative method. In this article, it was later found that first, informed consent itself is regulated in Law Number 17 of 2023 concerning Health, which was formed by the omnibus law method, and secondly that the legal procedure of informed consent for patients with mental disorders is regulated in Article 80 paragraphs (2) to paragraph (5), but does not yet have an implementing regulation, so the government must immediately form an implementing regulation.

1. Introduction
Health law is a critical field or concentration in legal science because it regulates the right to health as one of the human rights guaranteed in the International Bill of Human Rights. In essence – not only health – many fields outside of the law itself fall into the field of law because each field of science has its own laws to regulate how a field can be in accordance with the procedures and substances that should be. The feasibility in the health sector is in the field of law, as mentioned in the previous paragraph, which is health law (medical law). This health law does not have its codification in positive law in Indonesia. Still, other fields of law, such as criminal, civil, and administrative law, are closely intertwined with health science (Busro, 2018).

The basis of health law itself departs from the conventional approach; the law regulating body intervention has considered the body an object of analysis rather than a category of analysis. Legal analysis can offer a richer understanding of legal involvement with the body and body matter if it adopts a thicker embodiment conception. Such a conception would seek to explain how we value the living physical body because it makes our existence in the world and our interaction with others possible (Taylor, Dove, Laurie, &
Townend, 2018). The fields regulated by health law have a lot of substance, which essentially regulates the human body and the human right to health. The presence can know the legal relationship between doctors and patients in health law. Returning to the fields regulated in health law, it regulated the rights and obligations of doctors and patients, ethics and codes of ethics in the health profession, medical records, hospital functions and responsibilities, medical malpractice, euthanasia, etc (Claessen, Lamkaddem, Oomen, & Eijkman, 2023).

The development of international health law can be seen from the beginning of the World Congress on Medical Law in 1967 in Belgium, which later in the congress formed the World Association on Medical Law (WAML) to encourage the study and discussion of health law, medical law, and ethics, for the benefit of society and the advancement of human rights (Jones, 2021). WAML aims to promote the study of consequences in jurisprudence, legislation, and ethics of the development of medicine, health and related sciences. This right to health has become a constitutional right stipulated in Article 28H paragraph (1): “Everyone has the right to live a prosperous life physically and mentally, to live in, and to get a good and healthy living environment and the right to health services.”

This confirms that the right to health is inseparable from the health law, which is closely intertwined. This field, which is also not spared in health law, is about informed consent as an integral intertwining between the legal relationship of doctors and patients (Firdaus, 2023). Informed consent can be interpreted as informed consent or consent to the doctor's actions towards patients, which is one of the patient's rights and a form of special relationship between the doctor and the patient. This form of relationship is one tool that allows patients to determine their destiny in the doctor's practice (Wu et al., 2022).

Informed consent is a foundation in the legal relationship between doctors and patients. It can even be understood that this is by the conditions for the validity of an agreement stipulated in the Civil Code, namely in Article 1320, where the conditions for the validity of an agreement are an agreement between the parties that bind themselves to an agreement; the competence of the parties; There is a sure thing that is agreed and the causa is halal. Informed consent is closely related to the legal conditions of an agreement, which, in essence, means that the patient trusts a professional doctor (Scholten, Gather, & Vollmann, 2021). What is also important is the skills of the parties, be they patients or a professional doctor. But what is discussed in this article is what about informed consent to people with mental disabilities, which, in essence, is not included in the legal capacity because, in essence, the right to health does not look at whether the person has a mental disorder or not, the application of human rights is egalitarian and mental or mental health is included in the part of health and the right to health itself (Nurmaidiansyah, 2022).

In positive law in Indonesia, health or mental health is regulated by several laws and regulations. In the strata of law, there is Law Number 23 of 1992 concerning Health, repealed by Law Number 9 of 1960 concerning Health Principles. Law 23/1992 was repealed by Law Number 36 of 2009 concerning Health, and the most recent is Law Number 17 of 2023 concerning Health, which uses the method of forming omnibus law legislation. Some of the laws repealed by Law 17/2023 are Law Number 4 of 2019 concerning Midwifery; Law Number 6 of 2018 concerning Health Quarantine; Law Number 38 of 2014 concerning Nursing; Law Number 36 of 2014 concerning Health; Law Number 18 of 2014 concerning Mental Health; Law Number 20 of 2013 concerning Medical Education; Law Number 44 of 2009 concerning Hospitals; Law Number 29 of 2004 concerning Medical Practice; Law Number 419 of 1949 concerning the Hard Drugs Ordinance (Staatsblad 1949 Number 419).

As the researcher mentioned in the previous paragraph, one of the laws that were repealed in Law 17/2023 with this omnibus law method is Law 18/2014 on Mental Health, as will be the material for the researcher’s descriptive analysis in this research article where the scope or scope in this study is about how favourable laws that regulate are related to informed consent in Indonesia and how legal procedures are related to informed consent in people with mental disorders in the laws and regulations in Indonesia so that the existence of this research article will be an additional treasure of scientific science about informed consent in people with mental disorders.

2. Materials and Methods

As the researcher has described and explained comprehensively in the sub-background section, the research method used is normative legal research, which the researcher then uses to analyse favourable laws, both material and formal, about informed consent in people with mental disorders. The type of research that researchers use is analytical descriptive research, and the author uses it to describe how favourable laws are
both material and formal about informed consent in people with mental disorders. The researchers use both the statutory approach and the conceptual approach.

3. Results and Discussions

Ius Constitutum Informed Consent in the Indonesian Legal System

As the author has quoted previously in the sub-background section, in the legal system in Indonesia as a positive law is constituted, there is a development of regulatory law on health law, especially about informed consent. In the current positive law, namely in Law 17/2023, there are 458 articles which specifically discuss informed consent or action approval according to legal jargon in Law 17/2023, regulated explicitly in Paragraph 5, namely about approval of health service actions. The obligation of informed consent is regulated in Article 293 paragraph (1):

"Every individual Health Service action taken by Medical Personnel and Health Workers must be approved."

Article 293 paragraph (1) affirms the importance of this informed consent and that the nature of informed consent is mandatory because the phrase used is "shall" not "may", so based on grammatical interpretation, it can be understood that this article expressly affirms that this should not be an optional requirement only, but a mandatory requirement or prerequisite for continuing further medical action. This article also regulates all medical procedures and any patient condition, whether mentally normal or mentally disordered (Ismaningrum & Sari, 2017).

This further emphasises the informed consent of the doctor to the patient to emphasise the importance of consent or permission from the patient for a doctor's action so that it must meet adequate explanations, both related to diagnosis, indications, health care measures, risks and complications that may occur, risks if the action is not carried out and prognosis after obtaining action. Based on this coverage, it can be understood that it describes all medical actions given to patients and the effects that will occur if they are carried out. If they are not done so that patients have unequivocal information, they can consent (Mikael, 2020).

One of the things that the author has mentioned before, informed consent is closely related to the conditions for the validity of an agreement, in this case, competence; this is further regulated in paragraph (7): "If the patient concerned, as referred to in paragraph (6), is incapable of giving consent, consent for action may be given by the representative."

This paragraph confirms that informed consent to an incompetent person is given by the person representing the person, be it a parent, sibling, guardian or other person representing the incompetent patient. However, there are exceptions, as provided for in paragraph (9):

"If the patient's condition as referred to in paragraph (6) is incompetent and requires emergency action, but no party can be asked for consent, no action approval is required."

This exception is emphasised in matters that are indeed emergencies that require immediate health care and immediate action so that it does not require informed consent from its representative. Still, the health action information will then be shared with the patient after he has been competent or there is a representative who has attended, so the term for this is implied consent, which is often used in emergencies or implicit approval of medical measures. This incompetence can also occur in the context of the patient being a minor still under his parents' care; this is known as parental consent or proxy for the actions given to his child (Kumalasari & Ningsih, 2018).

In addition, informed consent is also related to health costs, as stipulated in Article 294 by healthcare facilities. However, for certain other matters, informed consent does not need to be given in the context of health services organised as a form of health service program from the government, but still needs to be informed to the patient; this is regulated in Article 295. In theory, there must be certain conditions worthy of being met in this informed consent, namely adequate information to patients about the need for medical action and the risks it can cause. Based on the information provided by the doctor, the patient gives his consent. Furthermore, the patient must consent to every diagnostic and therapeutic action (Aji, 2019).

Informed consent generally has another meaning with a complete intertwinedness: approval of medical actions related to consent, permission that must be given from the patient or the patient’s family related to the doctor before operating, or other invasive actions that have risks to patient health. Therefore, medical approval is often also mentioned with surgical licenses and patient consents, letters of agreement – between patients and doctors – and other terms known about this informed consent. Medical consent departs from 2 (two)
fundamental patient rights, namely the right to self-determination and the right to medical information. These rights are closely related to human rights principles in general.

**Legal Procedure for Informed Consent in Patients with Mental Disorders**

In general, it is widely accepted that competence or professionalism is a necessary condition for informed consent. In this viewpoint, if a person is incompetent to make a particular treatment decision, the treatment decision must be based on the prior direction or made by a substitute decision-maker based on a surrogate assessment standard, the best interest standard, or what can be called a competency model. On the scale of international law, there is a convention concerning mental or mental health, namely the United Nations Convention on the Rights of Persons with Disabilities (United Nations Convention on the Rights of Persons with Disabilities), which explains that persons with mental or mental disorders are included in the persons with disabilities themselves, as in Article 1:

“The purpose of the present Convention is to promote, protect and ensure the full and equal enjoyment of all human rights and fundamental freedoms by all persons with disabilities and to promote respect for their inherent dignity. Persons with disabilities include those who have long-term physical, mental, intellectual or sensory impairments which, in interaction with various barriers, may hinder their full and effective participation in society on an equal basis with others.

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This article in the UNCRPD confirms that persons with disabilities are included in terms of physical, mental, intellectual and sensory impairments in the long term, so in this case, it also confirms that this United Nations Convention cannot be separated from discussion in this scientific journal article that discusses health and informed consent.

The development of international health law itself underwent an expansion of medical engineering, the possibility for modern medicine to prevent rather than cure, and the fact that doctors are required to lead and direct the physiological life of man, especially in terms of work and family life. It is no longer a matter of healing arts but more and more of a privilege to work on the human body. From the point of view of "pure" legal theory, international health law is now a set of principles, standards and various institutions designed to ensure unequivocally and effectively the protection of human values that are symbols of human life and health. The intricate and complex activities carried out in this new branch of the law will have the objective of limiting the subject while at the same time harmoniously distributing it but giving rise in particular to the human character, impartial, universal and, as far as possible, independent of international medical law in the system of humanitarian law.

In Law 17/2023, informed consent for people with mental/mental disorders is precisely regulated, which is regulated in the eleventh section on mental health. The legal definition or meaning of mental health according to Law 17/2023 is contained in Article 74 paragraph (1):

"Mental health is a condition in which an individual can develop physically, mentally, spiritually, and socially so that the individual realises his or her abilities, can cope with pressure, can work productively, and can contribute to his community."

Furthermore, it can then be understood that this Law and this article that health itself is included in mental health and becomes unity with this omnibus law method so that the emphasis on the importance of mental health for a person can develop physically, mentally, spiritually and socially. The purpose of this mental health arrangement is a form of guarantee of the right to health as one of the undruggable human rights, worthy of achieving a good quality of life, enjoying a healthy mental life, free from fear, pressure and other disorders that tend to interfere with mental health and also as a form of guarantee for everyone to get various intelligence and psychological potentials. This is stipulated in paragraph (2) of it. Especially for informed consent for people with mental/mental disorders, the legal procedure is explicitly regulated in Article 80 paragraph (20):

"In the case of a person with a mental disorder who is deemed incompetent in making decisions, consent to action may be given by:
1. husband or wife;"
2. parents;
3. children or siblings who are at least 18 (eighteen) years old;
4. guardian or custodian; or
5. the office by the provisions of the law."

This confirms that there is a harmony between the positive law and theory in general, which asserts that incompetence can be resolved with the consent of the closest person to the incompetent patient – in this case, a person with a mental disorder – so that in this context incompetence in informed consent – as a form of engagement and agreement that is closely related to the conditions of the validity of an agreement – for the closest person can give people with mental disorders.

In the context of positive mental health law in Indonesia, initially regulated for the first time in Law 18/2014, precisely and explicitly regulates mental health – which will later be repealed by Law 17/2023 – but until now, the implementing regulations from Law 18/2014 until it is repealed by Law 17/2023 do not have to implement regulations, even though legally it is essential to support in the context of enforcement or implementation of the law (upholding the law). However, by the closing provisions of Law 17/2023, the implementing regulations of the law that were repealed and no longer valid due to Law 17/2023 remain in effect provided that they do not conflict with Law 17/2023, it is necessary to refer to the Minister of Health Regulation Number 290/MENKES/PER/III/2009 concerning Approval of Medical Actions which generally regulates the Approval of Medical Actions. However, it only regulates in general about informed consent, does not regulate informed consent for patients with mental/mental disorders, so the legal vacuum that currently occurs in the absence of further implementing regulations on mental health, especially the implementation of informed consent for patients with mental disorders.

Before the enactment of Law 17/2023, when Law 18/2014 was still in effect, there was no implementing regulation regulating informed consent for patients with mental disorders until the repeal of Law 18/2014 with Law 17/2023 with the omnibus law method. The transitional provisions order the government as an implementing agency to form and establish implementing regulations of Law 17/2023 within 1 (one) year, calculated from the promulgation of Law 17/2023; this is regulated in Article 456. Law 17/2023 was passed on August 8, 2023, so the government has until August 8, 2024, to form and establish implementing regulations from Law 17/2023, especially in this case, the implementing regulations of mental health, which then regulate informed consent for people with mental disorders in more detail.

4. Conclusion

In essence, informed consent to patients has explicitly been regulated in Law Number 17 of 2023 concerning Health, namely in paragraph 5 concerning Approval of Health Service Actions, regulated from Article 293 to Article 295, which is regulated in the strata of the Law, of course, which emphasises the importance of informed consent as one of the rights of patients to obtain information and explanations from medical parties who Then it becomes his right to self-determination and obtain medical information.

The legal procedure for informed consent for patients with mental disorders is regulated in Law Number 17 of 2023 concerning Health, in the eleventh part of Article 80, paragraph (2) to paragraph (5). In general, this law regulates mental health from Articles 74 to 85. What is currently lacking is informed consent in patients with mental disorders and certainly does not have legal competence – as one of the requirements for legal competence, but there are exceptions in the name of health – there is no implementing regulation from Law Number 18 of 2014 concerning Mental Health until the repeal of this law with Law Number 17 of 2023 concerning Health, So it is necessary for the government to immediately form implementing regulations or derivative regulations, especially in this case is the implementing regulation on informed consent for patients with mental disorders.
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