

# *The Implementation of Act 29/ 2004 concerning Medical Practice and Its Implementation Regulations*

Iman Firmansyah<sup>1</sup>, Asti Wasiska<sup>2</sup>, Rahmah Marsinah<sup>3</sup>

<sup>1</sup>Postgraduate Jayabaya University, Jakarta - Indonesia

<sup>2,3</sup>Faculty of Law, Ibnu Chaldun University, Jakarta - Indonesia

Email : [hifirmansyah.shmh@gmail.com](mailto:hifirmansyah.shmh@gmail.com)/[astiwasiska@yahoo.com](mailto:astiwasiska@yahoo.com)/[rahmah.lawyer@gmail.com](mailto:rahmah.lawyer@gmail.com)

*Abstract—Medical practice law is the answer to the doctor's responsibility in standardizing the profession. If the medical practice was done without fulfilling that pre-requirement, the medical practice administrators could be sentenced by administrative or juridical sanction. There are implementing regulations have not been prepared by the messages of Act 29/ 2004. The purpose of this research is to find implementing regulations of Act 29/ 2004 concerning medical practice that had been developed and had not yet been formed. The method of this research is normative descriptive research by some approaches. Law substances were collected from legislation and literature. This research has obtained some results, the Act of medical practice orders five health ministry regulations that had been developed, namely medical practice license, implementation of medical practice, approval of medical action, medical record, and mandatory keeping medical secret. There is one implementing regulation that has not been arranged, the regulation of electronic medical record, so currently use Act 11/ 2008 concerning information and electronic transaction to avoid the legal vacuum.*

**Keywords-** *act; electronic; medical; record*

## I. INTRODUCTION

Medical practice law (MPL) is the answer to the professional responsibility needed from the doctor as a minimal standard of medical practice. Service standards are the minimum limits that a doctor or dentist must meet in conducting medical practice. If these standards have not been met, the medical practice administrator may be subject to administrative or juridical sanctions. [1] On October 6, 2004, the government issued Act 29/ 2004 concerning Medical Practice (MPL) to provide patient protection, improve the medical service quality, and provide legal certainty to the public, doctor, or dentist. [2, 3] Each law is accompanied by implementing regulations as guidelines for implementing the law.

The actions and legal responsibilities of doctors as legal subjects can be related to their profession. Legal responsibility forces doctors to understand legal provisions, including understanding the rights and obligations in carrying out the medical profession. [4] The doctors also must understand legal obligations towards themselves and others. The legal obligation basically concerns what should be done or not in carrying out the medical profession, including obligations arising from the profession, as well as from therapeutic contracts with patients. A doctor's legal awareness must play a role in controlling himself so that he does not commit professional mistakes and avoid legal sanctions. [4, 5, 6] The issuance of the MPL raises the doctor's insight into the legal responsibilities of the medical profession. Doctors who do not have a Practice License (PL) do not necessarily commit malpractice. On the other hand, doctors who have PL may not always practice medicine according to professional standards. [4, 7]

Problems arise when a doctor was complained by his patient because he is considered to have leaked the patient's secret, even though he has kept the patient's secret. On the other hand, the electronic medical records that he uses to record patient medical records have not been regulated in the MPL implementation regulations, so no guideline explains who can access medical records, to what extent patient data can be accessed and disseminated, as well as some other things related to the disease and treatment of the patient. In this case, the researcher wants to explore the regulations for implementing the MPL that have been or have not been drafted so that in their application it is expected to cover the legal vacuum. Therefore this research is limited to the discussion of Law No.29/ 2004 concerning Medical Practice and its implementing regulations.

## II. PROBLEMS

Based on the above background, the problems in this study are:

1. What are the implementing regulations that have been compiled to fulfill the mandate in Law No.29/2004 concerning Medical Practice?
2. What are the implementing regulations which have not been compiled to fulfill the mandate in Law No.29/2004 concerning Medical Practice?

## III. RESEARCH METHOD

This study uses a normative juridical approach. Legal materials are sourced from legal literature to describe how many implementing regulations have been drafted and which are not as mandated by the MPL. By using a statute approach, legal materials are presented logically and systematically. Then study the MPL using a conceptual approach, and analyzed using an analytical approach to interpret the applicable legal provisions in responding to formulated legal problems.

## IV. DISCUSSION

### Laws and Regulations

#### Practice License and Implementation of Medical Practice

The MPL aims to protect both patients and doctors. Patients are people who need health services either directly or indirectly to doctors or dentists. Doctors and dentists are those who have graduated from domestic or international medical and dental education who are recognized by the government of the Republic of Indonesia by the legislation. [2] To obtain a PL, a doctor or dentist must have a valid Registration Certificate (RC), have a place of practice, and have a recommendation from a professional organization. The enforcement of professional discipline is supervised by the Honorary Council of Indonesian Medical Disciplines (HCIMD), an institution that has the authority to determine whether or not there is an error and impose sanctions for violations of scientific disciplines. The implementation of medical practice is controlled by competency-based registration. [6, 8] PL is issued at the request of an individual or agency to the District/ City Health Office where the medical practice is located.

Overseas graduates from Indonesian citizen doctor/ dentist must apply to the Indonesian Medical Council (IMC) to be evaluated at an accredited tertiary institution by statutory regulations based on a written request from the IMC. [2]

Doctor or dentist RC is given for a period of five years and can be re-registered for the next five years while still meeting the requirements and attaching the old RC. [2] RC can be revoked by the head of IMC on the recommendation of HCIMD and/ or the doctor is proven or stated that he is unable to practice medicine. The second and third PL during working hours is submitted by attaching a permit from the head of the agency concerned to work. Licensing is a government instrument with a juridical preventive nature as an administrative means to control public behavior. Linked to Law 9/2004 concerning amendments to Law 5/1986 concerning State Administrative Courts, licensing is a State Administrative decision. [9]

#### Approval of Medical Action

Informed consent is a subjective requirement for therapeutic transactions that rests on two human rights, namely the right to information and self-determination. Informed means being informed, and consent means to consent to do something. Informed consent is the consent given by the patient to the doctor after the patient has received an explanation. [10] Another definition of Informed Consent is the patient's agreement for the medical efforts made by doctors to help him after receiving information about medical efforts and all possible risks. [11, 12]

The most important part of informed consent is the information that is passed on to the patient or his family. It contains disease problems and actions to be taken, including the form, purpose, benefits, and risks of the therapy and its alternatives; the patient or family is given sufficient time to make a decision; who has to submit plans for surgical and other invasive measures; the information must be complete unless the doctor considers the information to be detrimental to the patient's health or refuses to be given information, then the information can be given to his family. [10, 11, 12]

Informed consent is conveyed expressly in words, both oral and written or secretly, delivered in perfect language, written or spoken, in imperfect language or sign language or silence but can be understood by the interlocutor. [4] Therefore, the form of informed consent is differentiated into oral or written expression and implied or tacit consent, that is, in normal circumstances or emergencies.

The doctor provides complete information that the patient can understand so that his consent decision can be justified. Patients provide honest and accurate information about their medical history so that treatment goals can be achieved. Informed consent is a tool to determine the fate of a patient and the fulfillment of the right to information to protect the patient's individual right to integrity from the doctor's illegal actions, and to protect the doctor from charges of violating the patient's right to integrity. The obligation to provide information for any medical action is to obtain patient consent. [13]

#### Medical Records

Is a collection of information on identity, results of history taking, examination and records of activities of health service providers for patients in the form of writings, pictures and results of medical examination [10] The Minister of Health Decree 134/ 1978 concerning the organizational structure and work procedures of the hospital which contains instructions for the implementation of hospital medical records carried out by the sub-division of medical records. [4]

Medical records serve as a means of communication between doctors and other health workers regarding services, medication, and patient care; basic treatment planning; written evidence of all services, disease progression, and treatment; basic analysis, study, evaluation of service quality; protect the legal interests of patients, hospitals and doctors, and other health workers; provide data for research and education purposes; the basis for calculating the cost of medical services; be a source of accountability and reports. [10] With the increasing number of malpractice charges, medical records have become very useful evidence for doctors who are charged with defending in court. [4]

#### Mandatory Keeping Medical Secrets

To maintain an atmosphere of mutual trust between doctor and patient, Hippocrates conveyed the importance of keeping the doctor's work secret. This obligation is contained in Government Regulation 26/ 1960 and Chapter II of the Indonesian Medical Code of Ethics. In its development, there are exceptions to disclosing the secrets of doctors' positions and jobs to maintain public interest and prevent things that can harm others. [14] About doctor's position and occupation secrets are emphasized in Government Regulation 10/ 1966 concerning Mandatory Keeping of Medical Secrets that the Minister of Health can carry out

administrative actions by Article 3 of the Health Law, or sanctions according to the Criminal Code.

Keeping medical secrets is a moral obligation that predates Hippocrates. [14] Position secrets are related to structural positions, while job secrets are related to functional tasks. The secret issue of a position from a legal standpoint, the behavior of a doctor is divided as follows:

1. Behavior related to daily work

Article 322 paragraphs 1 of the Criminal Code; that this law applies to every person whose job is to keep secrets, such as doctors, clergymen, and lawyers. Paragraph 2 relates to the doctor's position secret which is a complaint offense but threatens the offender who is still actively working or who has quit or has moved from his job. Article 1365 of the Civil Code explains that whoever makes a mistake which causes another person to suffer a loss is obliged to compensate for the loss.

2. Behavior under special circumstances

Every citizen can be summoned by the court to hear his testimony as a witness. A person who has certain skills can be called an expert. A doctor can be called as a witness, as an expert, or as an expert witness. [15, 16] As witnesses or expert witnesses, doctors can provide information about their patients. This conflict can be avoided by the right of resignation under article 277 of the Revised Indonesian Regulation. Likewise, in the Criminal Procedure Code articles 120, 168, and 170 paragraphs 2, the Chairman of the District Court or a judge who decides whether or not the reasons for witnesses or expert witnesses are appropriate or not to speak are acceptable. There may be a conflict of opinion from a doctor who believes that his statement violates the secret of office with a judge who does not accept the doctor's reason for exercising his right to resign. [15] The doctor's guideline for determining attitude is to prioritize occupational secrets as a moral obligation. The reason for releasing the secret of the position that must be taken is a process of reason, by considering the existence of a more important or public interest. [10] Medical secrets are also described in article 48 of MPL paragraph 4.

Implementation Regulations that have been made by the mandate of the MPL

1. Medical Practice License

The mandate of Article 36 MPL states that every doctor and dentist who practices medical practice is required to have a PL. [3] Article 38 paragraph 3 explains that the doctor's practice license will further be regulated by ministerial regulation. Health Minister Regulation (HMR) issued before and after the MPL comes into effect is as follows:

- a. HMR 916/ 1997 concerning Practice License for Medical Personnel
- b. HMR 1419/ 2005 concerning Implementation of Practices for Doctors and Dentists
- c. HMR 512/ 2007 concerning Practice License and Implementation of Medical Practice
- d. HMR 2052/ 2011 concerning Practice License and Implementation of Medical Practice

Article 36 HMR 2052/ 2011 states the revocation of HMR 512/ 2007 and is declared invalid, as well as the HMR which regulates the previous doctor's license.

Several differences with the previous HMR, including:

- a. Article 1 mentions the term doctor with additional clinical authority through education and training recognized by professional organizations to accommodate permits and authority to perform additional medical procedures.
- b. Article 3 paragraph 2 explains PL for internship program participant doctors who have the same authority as doctors.
- c. Article 3, paragraph 3 states that the PL for doctor participating in the Specialist Education Program is individual and is not given automatically.
- d. PL for foreign doctor or dentist is regulated in articles 17-19. Its scope is limited to providing training and providing services. Doctors or dentists who are foreign nationals may not practice independently, except for disaster relief with the permission of the authorities.

A doctor or dentist PL is given for three practice places in government, private and individual health service facilities in one province or different provinces. If in an area there are no doctors or dentists or other specialists, the doctor's PL applies to all government health facilities in that area. In certain circumstances, the doctor and dentist do not need PL in providing health services. These special circumstances are:

- a. Service fulfillment, but not continuous and unscheduled
- b. Perform social/humanitarian service

- c. State duties
- d. Disaster handling or other emergency assistance
- e. Giving help to family, neighbors, friends, home visiting services, and incidental assistance to the poor.

Service provider institutions above must notify the Head of the District/ City Health Services. PL is by the validity period of RC and can be extended as long as it meets the requirements in article 14 of HMR 2052/ 2011. PL extension proposals are submitted no later than three months before the validity period ends. If the RC expires, the PL can be extended using a receipt for RC management from a professional organization; valid for a maximum of six months. To fulfill the need for medical services, HMR 512/ 2007 and HMR 2052/ 2011 explain that the Head of Provincial Health Services on behalf of the Health Minister can provide a letter of assignment to a specialist doctor or dentist who has a PL working at a certain health care facility without requiring PL at that place based on the request of the Head of District/ City Health Services. Doctors and dentists who stop their medical practice are required to notify the local Head of District/ City Health Services in writing by returning the PL and receiving the original legalized RC photocopy from the IMC.

## 2. Implementation of Medical Practice

The implementation of medical practice is regulated in articles 20-28 of HMR 2052/ 2011, including the delegation of medical actions, carried out in writing when the need for services exceeds the availability of a doctor or dentist. The provisions regarding the delegation of medical action are as follows:

- a. The actions that are delegated are included in the competencies possessed by the recipient of the delegation
- b. The implementation of the action remains under the supervision of the grantor of the delegation
- c. The grantor of the delegation remains responsible for the actions delegated as long as the implementation is by the delegation given
- d. The actions delegated do not include making clinical decisions as to the basis for implementing the action
- e. The actions that are bestowed are not continuous.

According to Article 28 paragraph 1, social work by a doctor or dentist is carried out with the permission of the Head of District/ City Health

Services. If it is held outside the area, the organizer must ask permission from the local Head of District/ City Health Services by including doctors and dentists from the region. Social work by foreign nationals of doctor and dentist must be carried out in collaboration with doctor and dentist who have RC and PL in Indonesia with equal competence and obtain a permit from the local Head of District/ City Health Services.

### 3. Approval of Medical Action

HMR 290/ 2008 concerning approval for medical action contains an explanation of all medical actions against patients that require oral or written consent. Medical actions that have high risk must obtain written approval, except in emergencies and saving lives. The decision to take medical action is recorded and as soon as possible is explained after the patient is conscious or to the immediate family. Medical action approval can be canceled before the commencement of the action. Cancellation of approval for medical action is done in writing and it is the responsibility of canceling the approval. [3, 17]

Before obtaining approval for medical action, whether requested or not, doctor and dentist are required to provide explanations to patients and/ or their immediate family, including diagnosis, procedure and objective of the action, alternative procedure and their risk, risk and post-complication, measures, each prognosis, and estimates of the cost of each action. [3, 18] This is explained in Article 45 of the MPL, and a more detailed explanation is provided in HMR 290/ 2008. If it is thought that the explanation given can worsen the patient's condition or the patient refuses to be explained, then the explanation is given to the immediate family accompanied by medical staff as a witness. Even after obtaining medical approval, if there is negligence that results in a patient loss, it does not automatically cancel the legal responsibility that occurs.

The party entitled to give consent is a competent patient or his immediate family. If consent is given by a patient whose competence is in doubt, it can be canceled by the immediate family. This is explained in article 13 of HMR 290/ 2008. The patient's competence assessment is carried out by the doctor at the time the patient is asked for his consent, and in doubtful circumstances, the patient's competence is determined by a competent team of doctors. Approval of medical treatment for pediatric patients is given by the patient's parent or guardian, as is the

refusal of action. [12, 19] Refusal of acts that result in permanent physical or mental suffering to the child may be overturned by a court. [11] The regulations for the approval of medical action in special circumstances in HMR 290/ 2008 are as follows:

- a. In a state of mental illness which results in the patient being incompetent, approval for inpatient treatment is given to his immediate family
- b. Actions to discontinue life support for patients must obtain written approval from their immediate family

### 4. Medical Records

Article 47 MPL explains, that all provisions regarding medical records will be further regulated by a Minister of Health, namely HMR 269/ 2008 concerning Medical Records. Medical records are records and documents regarding the patient's identity, examination, treatment, actions, and other services that have been provided to patients. Every Doctor or Dentist is obliged to make a medical record according to the patient's condition at the time they are treated. The contents of the medical record are adjusted to the type of care the patient is undergoing. Article 3 paragraphs 1, 2, and 3 explain the content in the medical record of outpatients, inpatients or one-day care patients, and emergency patients. In a disaster situation, the content of the medical record is the same as the contents of the medical records of emergency patients plus information about the type of disaster and the location where the patient was found, the emergency category, and the patient number for the mass disaster, and the identity of the person who found the patient. [19, 20]

The medical record must be made and completed immediately after the patient receives health care, kept for at least 5 years from the date the patient was treated or discharged. After 5 years the medical record files can be destroyed unless the return home and approval of the action. Return resume and action approval is retained for 10 years from the date the resume was created. In non-hospital health service facilities, medical records are stored for 2 years, after which they can be destroyed. [19]

The content of medical records must be kept confidential by the doctor as well as the officer and leader of health service facilities. This information can be disclosed for reasons of patient health, request from law enforcement officials upon court

order, request and/ or consent of patients themselves, requests from institutions, research interests, education, and medical audits, as long as they do not mention the identity of the patient. Article 12 HMR 269/ 2008 explains the request for installation of the medical record for this purpose must be made in writing to the head of health service facilities. [21] The medical record file belongs to the health service facility, but the contents of the medical record belong to the patient. [18] The contents of the medical record are made in the form of a medical record summary. The summary may be provided, recorded, or copied by the patient or authorized person or with the written consent of the patient or patient's family entitled to it.

#### 5. Mandatory Keeping Medical Secrets

That all parties involved in health services are obliged to keep medical secret as regulated in article 48 of the MPL. In more detail, the HMR 36/ 2012 states that the obligation to keep medical secrets is valid forever, even though the patient has died. Article 5 HMR 36/ 2012 and Article 10 HMR 269/ 2008 concerning Medical Record in line with medical secrets can be opened only for the benefit of patient health, fulfilling requests from law enforcement officials in the context of law enforcement, patient requests, or based on the provisions of statutory regulations. The patient's health interests include health care, medication, care, and administrative needs, insurance payments, or health financing guarantees, after obtaining the relevant approval. Fulfilling the demands of the legal apparatus is the process of investigation, investigation, and prosecution, and court proceedings. This is done by providing data and information in the form of *visum et repertum*, expert statements, witness statements, and/ or medical summaries. [3, 17]

Disclosure of medical secrets based on statutory regulations for ethics and discipline enforcement is carried out at the written request of the Medical Ethics Council or HCIMD without the patient's consent. The disclosure of medical secrets in the public interest is carried out without disclosing the patient's identity. The public interest in article 9 paragraphs 4 HMR 36/ 2012 includes medical audits, threats of extraordinary events/ outbreaks of infectious diseases, health research for the benefit of the State, education or use of user information in the future, and threats to the safety of other individuals or society.

The medical secret disclosure is carried out by the doctor in charge of the service. If the patient is handled by the team, the team leader is authorized to open the secrets of medicine. If the person in charge of the service is not available, the one who can reveal the secrets of medicine is the head of the health facility. If the request to disclose medical secrets contradicts the provisions of laws and regulations, the doctor in charge of the service or the head of the health facility has the right to refuse to disclose the medical secret. [15, 17]

If a medical case of a patient dies, then the patient's family sues the health worker and/ or health care facility and informs it through the mass media, it is deemed to have released his right to medical secrets to the public. This means giving the authority to health workers and/ or health care facilities to disclose or disclose the medical secrets concerned as a right of reply. If a patient sues the health care facility, the respondent has the right to disclose medical secrets in court as a defense. [15, 17]

Implementing Regulations that have not been prepared by the mandate of the MPL

HMR 269/ 2008 describes the rules regarding electronic medical records that can be used as a legal basis for their application in Indonesia. Medical records must be made complete and clear in writing and electronically. According to Article 2 paragraph 2, it is said that the administration of medical records using electronic information technology is further regulated by separate regulations. It's just that until now there are no regulations that specifically regulate this electronic medical record. [21]

Electronic medical records are basically an innovation in the development of technology in health services in the form of changing forms from paper files to electronic records recorded in a computer system. Namely any notes, statements, or interpretations made by doctors or other health workers in the context of diagnosis and treatment of patients stored electronically based on sheets of medical record files in a computer system. [21] What needs to be considered in the implementation of the electronic medical record:

- a. Patient Identification System and Medical Record Numbering
- b. Patient Flow Process and Patient Documents
- c. Policies in medical activity services that must be adapted to digital procedures, namely:
  - Filing immediately on the computer

- Identity code as a substitute for initials or signature
- Use of a personal identification number for data changes
- Digital medical record form for outpatient/ inpatient/ emergency department respectively
- Medical Record processing

The legal strength of electronic medical records is still a matter of debate, so not all health facilities have implemented it. The reference that regulates electronic transactions in general is Law 19/ 2016 concerning Electronic Information and Transactions instead of Law 11/ 2008 concerning Electronic Information and Transactions (EIT Law). Electronic medical record data is the property of the patient, so it must be kept and guaranteed its confidentiality by the applicable laws and regulations. This obligation is the duty of the doctor or dentist and head of the health facility. The other side that can cause problems is patient confidentiality and privacy. If the medical data falls into the wrong hands, it can cause legal problems for which the responsibility lies with the doctor or hospital management. Therefore, the implementation standard for making and storing medical records that apply to paper files must be applied to electronic files. Some identity data, informed consent, results of consultations, laboratory, and radiology results must remain on paper. The World Council of Physicians' Association in the field of ethics and law issued a provision in 1994; some important pointers are:

- a. Medical information is entered on the computer by authorized personnel
- b. Patient data must be kept strictly according to the security level
- c. Information can be disclosed only with patient consent
- d. Expired data is deleted after notifying the doctor and patient/ heir
- e. The online terminal computer is only used by authorized personnel

The electronic medical record must implement a security system that can prevent information leakage. [20] Each user has a PIN and password or uses a fingerprint or iris pattern as identification. Doctors who do not fill in medical data are still responsible for the contents of the medical records. Electronic medical record security includes assigning personnel to access the system, installing programs and repairing the system; provides for an amendment to data errors; password for operator

authentication; not using the computer at the same time; log out before leaving the computer and use an electronic signature.

Medical records are the main written evidence, so they are useful in solving legal, disciplinary, and ethical problems. Used in court as an official document of responsible hospital activities. Original medical record documents can be provided upon court request with proof of receipt. If there is any doubt regarding the contents of the medical record, expert witnesses may be presented by the court to seek an expert opinion. This also applies to electronic medical records based on Law 11/ 2008 concerning EIT. According to article 44, legal evidence other than those stipulated by law and regulation includes other evidence in the form of electronic information. Electronic medical records include legal evidence according to the provision of the law. [18] Because electronic medical records are valid evidence, it is necessary to pay attention to the security of the computerized system. The electronic medical record security system includes the security of computer networks from hacker attacks, data theft, viruses, and other types of malware attacks, as well as the security of the computer itself.

The doctor-patient relationship is generally a therapeutic relationship, but with the medical transaction, it becomes a legal relationship. Both parties need to know their rights and obligations in case of legal problems at a later date. Among the principles that underlie the legal relationship between doctors and patients is the principle of legality which means if they meet the requirements and permits stipulated in the MPL, as well as the principle of honesty. This principle is the basis for the delivery of correct information, both of two parties.

The obligations of the doctor towards the patient are contained in the Indonesian Medical Code of Ethics (IMCE) articles 10-13, and are clarified in articles 50-51 of the MPL, while the rights and obligations of patients are contained in articles 52-53. Violation of these obligations may result in the doctor being subject to criminal threats. Article 50 MPL states that doctors and dentists have the right to obtain legal protection, and obtain complete and honest information from patients or their families. Other physicians' rights include the right to terminate their relationship with the patient if the patient does not comply with the advice given, the right to the patient's good faith in carrying out therapeutic transactions, and the right to privacy. In

this connection, the patient's obligations as outlined in article 53 arise, namely to provide complete and honest information about their health problems, comply with doctor's advice and instruction, comply with the applicable provision in health care facilities, and provide compensation for services obtained. This means that the error can be made by the patient himself (contributory negligence), or the patient is not honest in providing information or providing misleading information so that the disease will get worse and die, so the doctor cannot be blamed.

IMCE also stated the patients' rights, including the right to life, the right to their own body and the right to die naturally, the right to obtain humane medical services, the right to obtain an explanation regarding diagnosis and therapy, the right to obtain planned diagnostic and therapeutic procedures, the right to refuse or accept participation in medical research, the right to be referred to a specialist, the right to the confidentiality of medical record, and the right to obtain an explanation of hospital regulations. Based on articles 51-52 of the MPL, doctors are obliged to provide medical services as well as patient medical needs, refer the patient to another doctor who has better expertise or ability, keep everything a secret he knows about the patient, even when the patient has passed away, and performs emergency aid on a humanitarian basis.

## V. CONCLUSION

The MPL mandates five ministerial regulations, namely medical practice license, implementation of medical practice, approval of medical action, medical record, and mandatory keeping medical secrets. The five ministerial regulations have been prepared by the mandate of the MPL, but in the medical record section, it is stated that electronic medical records will be regulated by a ministerial regulation because electronic medical records are different from the manual medical record. Due to the absence of regulations regarding electronic medical records, currently, Law 11/ 2008 concerning EIT is used.

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