

THE SUBJECTS WHO ARE OBLIGED TO ENSURE THE CONFIDENTIALITY OF PATIENT INFORMATION IN MEDICAL EXAMINATION AND TREATMENT ACTIVITIES IN VIETNAMESE LAW

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Abstract: This article discusses the subjects who are obliged to ensure the confidentiality of patient information in medical examination and treatment activities according to HIPAA and Vietnamese law. On that basis, the article makes recommendations to improve these legal provisions on this issue in Vietnamese Law.

Key words: ensure the confidentiality of patient information;

1. The Subjects Who Are Obligated To Ensure The Confidentiality Of Patient Information In Medical Examination And Treatment Activities According To HIPAA

In medical examination and treatment activities, patient information is all data in medical records and other private information that the patient has provided to health care facilities and providers during the medical examination and treatment process.

HIPAA, also known as the Health Insurance Portability and Accountability Act, is a US Federal Law that ensures baseline privacy and security standards for Protected Health Information (PHI). It uses a series of criteria to determine if an entity needs to be HIPAA compliant. And in case any covered entity violates HIPAA regulations (knowingly or unknowingly), it can face civil action lawsuits, criminal charges, and hefty monetary penalties ranging between \$100-\$1.5 million per violation¹.

The HIPAA rules apply to any individual, healthcare organization, and cloud-hosted company that meets the definition of a covered entity as stated in HIPAA guidelines.²

1.1. Covered Entities

There are various kinds of entities that fall under the Covered Entity category. *Firstly*, healthcare Providers are the any healthcare organization or institution that collects protected health information (PHI) must be HIPAA compliant. This includes doctors, dentists, psychologists, physiologists, clinics, pharmacies, nursing homes, etc. *Secondly*, healthcare Plans – Any corporations that give healthcare plans such as health insurance companies, group health plans, health maintenance organizations, and government-funded health plans like Medicare & Medicaid

¹Atchinson, Brian K.; Fox, Daniel M. (2021), "The Politics Of The Health Insurance Portability And Accountability Act" (PDF). Health Affairs. 16 (3): 146–150.

²Ken (2019), "Patient Privacy - The New Threats", Machine Physicians Practice journal, volume 19, number 3.

are a covered entity. *Lastly*, healthcare clearinghouses – All healthcare clearinghouses that convert PHI data into a uniform format for electronic transmission also fall under covered entities.

1.2. Business Associates

A business associate is any person or entity that executes certain operations or responsibilities that involve disclosing or using the PHI, either on behalf of or as a service provider to a covered entity. Business associates don't require direct interaction with patients to perform their services for covered entities. However, the covered entities must execute a business associate agreement (BAA) to ensure their partnered business associates safeguard the shared PHI as per HIPAA regulations. In addition, business associates are directly liable for any HIPAA violation and are subject to the same penalties that apply to covered entities.³

1.3. Subcontractors

A subcontractor is an individual or entity that creates, maintains, and transmits health information on behalf of a business associate. In fact, a HIPAA subcontractor bears the same legal responsibilities as any business associate we discussed earlier. For example, a covered entity's business associate may hire an external agency to destroy documents containing the PHI or avail a cloud service to store & process the PHI. In both scenarios, the external agency falls under the Subcontractor category and is required to comply with most of the HIPAA regulations.⁴

1.4. Hybrid Entities

A hybrid entity usually conducts both HIPAA-covered and non-covered tasks as a business. A perfect example of this is any large organization that has a self-insured healthcare plan for its employees. In this type of organization, only a part of the company is considered a covered entity, and only that part (also called the health care component) is subject to HIPAA compliance. An organization that is a hybrid entity must ensure that its healthcare component does not disclose the PHI to any non-covered component within the organization.⁵

1.5. Researchers

HIPAA regulations allow covered entities to share PHI with researchers if patients have given their consent to disclose and use their PHI for research. In such cases, there is no need to sign a business associate agreement. However, the covered entity must draw and enter a data use agreement with the partnered researcher before disclosing the PHI⁶.

2. Subjects Have The Obligation To Ensure Confidentiality Of Patient Information In Medical Examination And Treatment Activities In Vietnamese Law

³See 45 CFR Sections 160.102 and 160.103

⁴ See 45 CFR 164.522

⁵ See 29 U.S.C. § 1181(a)(2)

⁶ Traynor, Kate (2022), "HIPAA compliance date for electronic transactions extended". American Journal of Health-System Pharmacy, p.214 -217.

2.1. Medical examination and treatment practitioners- Subjects directly holding patient information

The subjects that directly hold patient information in medical examination and treatment activities are medical examination and treatment practitioners because these subjects have direct access to patient information (Collect, manage and use patient information). These entities collect patient information in many different ways such as: Ask the patient directly, observe the patient's symptoms, monitor the disease condition, accidentally see or hear images and information of the patients throughout the medical examination and treatment process. Therefore, according to Vietnamese law, these entities are obliged to ensure the confidentiality of patient information⁷.

In 2023, the Vietnamese National Assembly issued the Law on Medical Examination and Treatment, effective from January 1, 2024. According to the provisions of this law, keeping patient information confidential is stipulated in Clause 2, Article 10 - Right to be respected for health protection and privacy in medical examination and treatment : "*The information in medical records and other information about private life that the patient has provided to the practitioner during the medical examination and treatment process is kept confidential, unless the patient agrees to share it.*"

In addition, Decision No. 4054 (September 22, 2020) of the Vietnamese Ministry of Health promulgated *Temporary Guidance and Regulations on Remote Medical Examination and Treatment*. In these legal provisions, the obligation of medical examination and treatment practitioners is to ensure the confidentiality of patient information in many aspects:

Firstly, measures to limit sharing of patients' personal information during remote medical examination and treatment (a) “ *Do not share personal information of the patient such as: Full name, address, image of the patient's face, body or information that can identify the patient in any form (via images, text, audio recordings...);* (b) “*In case the consultation requires the presence of the patient, technical measures must be used to cover or blur the image of the patient's face.*” ; (c) *Do not conduct "Live stream" via social networks or other forms that may reveal personal information, images of the patient's face, the health situation of the patient, and those participating in remote medical examination and treatment*⁸.

Secondly, the responsibilities of medical examination and treatment practitioners participating in remote medical examination and treatment, The Guidance and Regulations require medical examination and treatment practitioners to participate in remote medical examination and treatment (a) *to keep the patient information confidential and (b) not to share these information.*⁹

Some other legal documents and administrative documents such as: Law on People's Health Protection 1989 (Clause 1, Article 25); Law on Prevention and Control of Infectious Diseases 2007 (Article 33); Law on Prevention and Control of Virus That Causes Acquired Immunodeficiency Syndrome (HIV/AIDS) in 2006 (amended in 2020) (Article 30) are the

⁷ Clause 2, Article 3 of the 2009 Law on Medical Examination and Treatment

⁸ Section 4 of the Temporary Guidance and Regulations on Remote Medical Examination and Treatment

⁹ Section 4 of the Temporary Guidance and Regulations on Remote Medical Examination and Treatment

important bases to affirm the obligation to ensure confidentiality of patient information of medical examination and treatment practitioners in medical examination and treatment activities in Vietnam.

2.2. The Patients – The Owners of patient information

Patients are the owners of their own information, so they have full rights to possess, use and dispose of their information. However, a patient's right to information is also associated with the patient's obligation to ensure the confidentiality of patient information in some specific cases. This means that if the patient does not ensure the confidentiality of his or her own information in some cases, other subjects will have many opportunities to access this information easily. From this, buying, selling, and disclosing patient information will become increasingly complicated. Therefore, the patient's obligation to ensure the confidentiality of patient information in some cases also has a particularly important meaning in practice, especially in the current era of fast and strong development of digital technology.

We must also acknowledge that the patient's obligation to ensure confidentiality of patient information is not an absolute and pervasive obligation in all circumstances, at all times and in all cases. On the contrary, patients have the absolute right to provide and disclose their own information when they are aware that sharing information in those cases is necessary for themselves and is not harmful to other subjects. It can be affirmed that this is a notable difference in the patient's obligation to ensure patient information confidentiality compared to the obligation to ensure patient information confidentiality of other subjects.

Currently, the patient's obligation to ensure confidentiality of patient information is only stipulated in Decision No. 4054 (Point c, Section 5 of the Temporary Guidance and Regulations on Remote Medical Examination and Treatment): *“Participating in remote medical examination and treatment, the patient or the patient's legal representative do not reveal identity and other patient information.”*

2.3. The Third Subjects - Related Subjects

The third subject is those who obtain patient information through patient authorization, professional activities, study activities, scientific research or official duties. These entities are not the owners of patient information and are not the direct holders of patient information. Therefore, to be able to collect and use patient information, these subjects will have to perform the act of "request/ask" medical examination and treatment practitioners or patients to provide patient information to them. Disclosing and leaking patient information will not harm these subjects themselves, so they will tend to disclose and "trade patient information" to profit or satisfy their needs. Therefore, it is especially necessary and important that the law clearly stipulates the obligations of these entities in ensuring the confidentiality of patient information. This is the legal basis to prevent acts of disclosing patient information and causing damage to patients. Article 69 of the Law on Medical Examination and Treatment (2023) stipulates the obligations of these entities when they use patient information in medical records and they are only allowed to use patient information for the right purpose as originally requested.

3. Recommendations To Improve The Legal Provisions On The Subjects Who Are Obligated To Ensure Confidentiality Of Patient Information In Vietnamese Law

Both US law and Vietnamese law stipulate that the obligation to ensure confidentiality of patient information is the obligation of many subjects. However, US law stipulates these subjects clearly, fully and specifically. In addition, US law also stipulates specific methods and instructions for these subjects to fulfill their obligations to ensure patient information confidentiality. On the contrary, Vietnamese law does not fully regulate these subjects. In addition, the methods and instructions for these subjects to fulfill their obligations are also being ignored. Therefore, in Vietnam, subjects with an obligation to ensure patient information confidentiality tend to violate this obligation unintentionally or intentionally. From this, the author make number of recommendations to improve the legal provisions on this issue in Vietnamese Law:

Firstly, regarding the obligation to ensure confidentiality of patient information of medical examination and treatment practitioners, this subject's obligation to ensure confidentiality of patient information was clearly recorded in Clause 2, Article 3 of the 2009 Law on Medical Examination and Treatment as one of the principles in medical examination and treatment. However, Article 3 of the 2023 Law on Medical Examination and Treatment has eliminated this principle. According to the author, this is a "step backwards" for the current law because we cannot deny the importance of this principle in the process of practicing medical examination and treatment. Therefore, the author recommends that the coming version of this law should add the principle "Respect the rights of patients; keep information about health status and private life recorded in medical records confidential".

Secondly, regarding the patient's obligation to ensure confidentiality of patient information in some specific cases, it can be seen that patients are the owners of their information. Therefore, they have full rights to their own information. It can be said that patients do not have the right to "disclose" your information to others in all cases, they also have an obligation to ensure the confidentiality of their own information.

Currently, Vietnamese law does not clearly stipulate in which cases patients are obliged to ensure the confidentiality of their own information (there are only the cases specified in point c, section 5 of the Temporary Guidance and Regulations on Remote Medical Examination and Treatment (in Decision No. 4054)). Such a legal situation will give rise to a number of inadequacies in practice, which are: (i) which subjects and which circumstances is the patient obliged to ensure information confidentiality?; (ii) Are patients only obliged to ensure the confidentiality of their information during remote medical examination and treatment?; (iii) During direct medical examination and treatment activities, do patients need to ensure the confidentiality of their information? Therefore, the author proposes that in the 2023 Law on Medical Examination and Treatment, there should be legal rules clearly stating: Which cases are patients obliged to ensure the confidentiality of their information during medical examination and treatment activities? Which subjects do patients need to ensure the confidentiality of their information?

Thirdly, regarding the third party's obligation to ensure patient information confidentiality, the third party is currently obliged to ensure the confidentiality of patient information as prescribed

in Clauses 3 and 4, Article 69 of the 2023 Law on Medical Examination and Treatment and Point d, Section 5 in Decision No. 4054.

These are important legal provisions for the third parties to fulfill their obligation to ensure confidentiality of patient information. However, there are still many third parties whose obligation to ensure the confidentiality of patient information have not been specified in Clauses 3 and 4, Article 69 of the 2023 Law on Medical Examination and Treatment. Therefore, the author proposes to add to point a, clause 4, Article 69 as follows: “*Covered entities, business associates, subcontractors, hybrid entities and researchers are also obliged to ensure the confidentiality of patient information during medical examination and treatment activities*”.

REFERENCES:

1. Decision No. 4054 (September 22, 2020) of the Vietnamese Ministry of Health
2. The US Health Insurance Portability and Accountability Act
3. The Vietnamese Law on Medical Examination and Treatment 2023
4. The Vietnamese Law on Medical Examination and Treatment 2009
5. The Vietnamese Law on People's Health Protection 1989
6. The Vietnamese Law on Prevention and Control of Infectious Diseases 2007
7. The Vietnamese Law on Prevention and Control of Virus That Causes Acquired Immunodeficiency Syndrome (HIV/AIDS) 2006 (amended in 2020)
8. Atchinson, Brian K.; Fox, Daniel M. (2021), "The Politics Of The Health Insurance Portability And Accountability Act" (PDF). *Health Affairs*. 16 (3): 146–150.
9. Ken (2019), "Patient Privacy - The New Threats", *Machine Physicians Practice journal*, volume 19, number 3.
10. Traynor, Kate (2022), "HIPAA compliance date for electronic transactions extended". *American Journal of Health-System Pharmacy*, p.214 -217.