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# Research on Authenticity Appraisal of Electronic Medical Records from the Perspective of Litigation

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## Abstract
*Medical records record the whole process of diagnosis and treatment behavior of medical institutions, and have irreplaceable evidence value in the litigation process of medical dispute cases. The electronic medical record is different from traditional paper as digital evidence; in the trial of medical disputes, its authenticity should be confirmed by electronic data identification in the field of judicial expertise. In view of this, this paper focuses on the authenticity identification of electronic medical records, in order to solve them as a new litigation evidence to lay a scientific foundation.*

## Keywords
*electronic medical record; forensic expertise; litigation evidence*

## 1 Introduction

Since the Ministry of Health launched the Basic Standards of Electronic Medical Records (Trial) in 2010, medical record management has shifted to digital transformation. Compared with traditional paper medical record, electronic medical records are not physically visible, and their complex digital coding forms an impenetrable barrier between doctors and patients. In the case of medical disputes, the mediation committee or the court usually entrusts a qualified professional appraisal institution to evaluate whether the medical behavior is negligent, and the key basis of the evaluation is the medical record of the patient during the treatment. Since the EHR is stored in the hospitals electronic system, the authenticity of the EHR may be questioned if the patient finds that the actual situation during the treatment is inconsistent with the records in the EHR. In judicial practice, there is still some ambiguity about the authenticity of electronic medical records, which provides a large space for the free ruling of appraisal institutions and courts. The author will discuss how both doctors and patients should evaluate the authenticity of the electronic medical records.

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# 2 The Concept and Origin of Electronic Medical Records

## *2.1 What Is Electronic Medical Records*

Medical records can be divided into paper medical records and electronic medical records. Internationally, electronic medical records have a variety of different names, each of which represents different concepts and application scope. The United States was the first to propose the concept of electronic medical records, which is defined as digital medical records stored in computers. It also launched the project called "Application of Health Information Technology in Economy and Clinical Practice" (HITCH), and put forward the core concept of "meaningful use". In Japan, electronic medical records is defined as records that meet the authenticity, readability and security requirements, which are stored electronically and maintained under prescribed regulatory rules. In medical disputes, only these records are provided to the patients and their agents. The International Association for Electronic Medical Records (eComputer-based Patient Record Institute, CPRI) defines electronic medical records as the technology of obtaining, storing, processing, keeping confidential, ensuring, transmitting and displaying medical information about patients .At present, the international concept of electronic health record (Electronic Health Record, EHR) is more common. The EHR is the electronic record of personal health-related activities, including not only the record of people receipt of medical services, but also the record of immunization, health care services, participation in health education activities and so on.In 2010, the former Ministry of Health (now the National Health Commission) gave the official definition of electronic medical records for the first time in the Basic Specifications for Electronic Medical Records (Trial). According to article 3 of the code, electronic medical records refer to the medical records of medical personnel, using the text, symbols, charts, graphics, data, images and other digital information generated by the information system of medical institutions, and can be stored, managed, transmitted and reproduced. It is a recorded form of medical records. Medical records edited and printed using word processing software do not belong to the electronic medical records mentioned in this specification.

In 2017, the former National Health and Family Planning Commission (now the National Health Commission) revised the Basic Standards for Electronic Medical Records (Trial) issued in 2010, forming the Standards for the Application and Management of Electronic Medical Records (Trial). According to the provisions of article 4 of the specification,Electronic medical records refer to the medical records that can use text, symbols, charts, figures, figures, images and other digital information generated by medical personnel in the process of medical activities, and can store, manage, transmit and reproduce medical records. It is a record form of medical records, including door (emergency) medical calendar and inpatient medical records.In a word, electronic medical records are not a simple computerized or electronic storage form of traditional paper medical records, but a digital information integration of all data directly generated by medical institutions and reflecting the process formed during patient diagnosis and treatment based on specific information systems.

It can be seen that electronic medical records are not only medical record information input on the computer, but an information system based on a database server, which can manage and use digital information across multiple terminals.

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### *2.2 The Evolution of the Evidence Qualification of Electronic Medical Records*

In China's current legal system, there is no law and regulation specifically for electronic medical records. According to the Civil Procedure Law of the People's Republic of China newly revised in 2023, article 66 evidence includes: (1) statements of the parties; (2) documentary evidence; (3) material evidence; (4) audio-visual materials; (5) electronic data; (6) testimony of witnesses; (7) appraisal opinions; and (8) inquest records. The evidence must be strictly verified and can only be used as evidence to confirm the facts. In the electronic medical record information, covers the characters, numerical (such as all kinds of laboratory data), text information (such as the patients complaint), sound recording (such as heart and lung sounds), all kinds of physiological graph, static image data and dynamic video images, these information are stored in the database server multimedia digital, as electronic data evidence attributes.

## 3 The Legal Consequences and Standards of Authenticity Authentication of Electronic Medical Records

### *3.1 Legal Requirements for the Identification of the Authenticity of Electronic Medical Records*

According to the "Expert Consensus on the Authenticity of Medical Records" issued by the Institute of Evidence Science of China University of Political Science and Law in 2024, the authenticity of electronic medical records refers to the nature that the content, logical structure and background of electronic medical records are consistent with the original situation at the time of formation. The electronic medical records with authenticity are formed by the safe and reliable medical record system software used by medical institutions, without illegal tampering or misuse, which can prove that the intention, generator or sender, and the time of generation or sending are consistent with the established one, and all modifications leave traces and can be traced to the source.

On December 25,2019, the Supreme People's Court officially issued the decision on amending the Provisions on Evidence in Civil Procedure (hereinafter referred to as the Provisions on Evidence). One of the highlights of the new rules is the established criteria for reviewing the authenticity of electronic data. According to the in-depth interpretation of the Evidence Provisions, the integrity and reliability of electronic data must follow the principles of non-destructive nature, professionalism and integrity. When it comes to the review of electronic medical records, first of all, the principle of nondestructive nature emphasizes the originality of electronic medical records and forbids any tampering and falsification, which has become the main point of dispute in doctor-patient disputes. Secondly, the principle of professionalism points out that when the parties raise questions or the judge cannot form a certainty through comprehensive judgment, the relevant technical issues can be explained with the help of appraisal, inspection or expert appointment as appraisers or expert assistants. Finally, the principle of integrity involves two aspects: the completeness of EHR content; the other is the completeness of EHR operation records. If the electronic medical records are incomplete and the medical institutions cannot provide a reasonable explanation, their authenticity should be questioned.Article 12 of the "Electronic medical record Application Management Standard" revised in

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2017 clearly points out that electronic medical records should follow the principle of authenticity, and require the whole process of recording marks, compared with the provisions before the revision, the requirements for recording marks are more stringent, and the scope of the mark is expanded from "modification behavior" to "operation behavior", including the trace, time and operator information of each operation.

### *3.2 The Legal Consequences of the Authenticity Appraisal of Electronic Medical Records*

Ensuring the authenticity of the EHR is essential to establishing its connection with the facts of the case. Only when these records are proven to be accurate can they provide a true picture of medical activities and establish objective links to the issues at issue in the case, thus providing a reliable basis for the judge's decision. As for the relevance and compliance of the EHR, judges can independently evaluate it based on a comprehensive review of the case and the relevant legal provisions. However, if the two parties seriously disagree on the authenticity of the electronic medical record, and the judge cannot rely on the legal knowledge alone, it is necessary to introduce the appraisal of professional appraisal institutions.However, it should be noted that, due to the limitations of the current technology, some problems may still be difficult to solve through identification. Therefore, the authenticity identification of electronic medical records is not only more complex and challenging, but also the identification results have a profound impact on the follow-up trial of the case.

The appraisal results of the authenticity of electronic medical records may have the following three different effects on the follow-up trial of the case:

（1）The electronic medical records provided by medical institutions are relatively complete, and the diagnosis and treatment facts and records confirm each other, and the authenticity of electronic medical records can be determined. Real electronic medical records are one of the important basic materials for the follow-up review of whether medical institutions constitute infringement.

（2） If the medical institution refuses to provide medical records or cannot provide medical records, the fault can be directly identified according to the principle of presumption of fault. Such as in "a hospital and Liu medical damage liability dispute case" in the court that medical institutions timely writing keep medical records is the basic obligation of medical institutions, its ability to grasp the evidence significantly better than patients, because it refused to provide the behavior of medical records is serious, bad, to balance the interests among the patients, the law directly presumption at fault. As for the necessity of autopsy, with the analysis of the reasons of Nanjing Jinling Judicial Appraisal Institute, it is not excluded that under the premise of objective and comprehensive medical record data, even if the autopsy will inevitably affect the identification of medical fault and causal relationship. To say the least, even if the responsibility for refusing or delaying the autopsy lies with the patient, the patient is at fault. Combined with the above analysis, the responsibility for the relevant appraisal of this case lies in the hospital.

（3） If the electronic medical record is modified, the medical institution shall bear the burden of proof that the modified content does not affect the substantive content. In such cases, the court may start the electronic medical record appraisal procedure according to the authority or upon the application of the patient.

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If the electronic medical records are indeed forged or falsified, the court may determine that the medical institutions have different degrees of fault, but whether the medical institutions ultimately need to bear the tort liability, they should continue to examine the fault of forging and tampering with the electronic medical records, the causal relationship between the diagnosis and treatment behavior and the damage consequences. If the loss of authenticity of the medical records due to the medical institution directly determines the causal relationship and the fault degree between the behavior of the medical institution and the damage consequence of the patient, the medical institution shall be liable for the loss caused by the medical behavior.

In the "medical damage liability dispute between Sun and a hospital", the court heard that in view of the medical records is indispensable and important data for medical appraisal,is to find out the facts of the medical damage dispute, it is an important basis for determining whether the medical behavior implemented by the medical institution is at fault and whether there is a causal relationship, the objectivity, authenticity and completeness of the medical records are the premise of judicial fault identification.Defendant, as the formation and depository of the medical records,.Have the obligation to provide complete and true medical records to the appraisal institution, after the present identification, the absence of the electronic medical record of the defendant, it shall bear the adverse consequences of failing to provide true and complete evidence. According to the relevant laws, there should be a causal relationship between the death of the defendant and the patient Liu Ying, Therefore, the defendant should bear the compensation liability for the damage result of the patient Liu Ying.

（4）If the electronic medical record is modified, but only has the form defects such as wrong words, not written in the standard format of the medical record, the identification of the authenticity of the electronic medical record will not be affected. For example, in the "Liang and a hospital medical damage liability dispute", the court held that the so-called forgery, refers to the intentional manufacture of false documents to achieve the purpose of misleading others. The so-called tampering refers to the use of false means to change the original text or distort the original meaning. In the medical records recorded by the defendant, there are some signatures between the medical staff, the contradictory recording time, and many mistakes in the inpatient department. However, these contents are not key words and important data, which cannot affect the judgment of the defendants medical behavior. At the same time, the plaintiff did not require the authenticity of the electronic medical records. Based on the flaws in the medical records, we cannot conclude that defendant falsified or tampered with the medical records.

According to Article 1222 of the "Civil Code of the People's Republic of China" (Tort Liability), "The medical institution is presumed to be at fault if the patient is harmed in the course of diagnosis and treatment under any of the following circumstances: (1) Violating laws, administrative regulations, rules, and other relevant diagnostic and treatment norms; (2) Concealing or refusing to provide medical record materials related to the dispute; (3) Losing, forging, tampering with, or illegally destroying medical record materials."If the plaintiff cannot provide evidence to prove that the defendant violates the provisions of this article, it cannot presume that the medical institution is at fault. Because the plaintiff fails to provide effective evidence of his claim, it should bear the consequences of failing to provide evidence, the plaintiff's claim will not be supported.

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# 4 Problems Existing in the Authenticity Identification of Electronic Medical Records

In the field of law and medicine, the authenticity judgment of medical record evidence is a complex issue, which involves not only legal expertise, but also medical expertise and even computer data. The authenticity of medical records, especially their medical and computer data attributes, often exceeds the scope of the professional ability of judges, making it difficult for judges to give a deterministic evaluation. This dilemma may lead to a deadlock in the handling of cases: the court does not recognize the authenticity of the medical record evidence, the identification body can not identify, without the identification result, the court is difficult to make a final decision.. This situation is not a simple problem of right and wrong, but caused by the defects of the existing legal rules, which is mainly reflected in the lack of clear provisions on the authoritative identification subject, identification standards and sealing procedures of the authenticity of medical records.

## *4.1 The Legal Standards for Determining the Authenticity of Electronic Medical Records Are Fuzzy*

Determining the authenticity of an EHR is key to assessing its legal effect, which concerns how judges assess the credibility of the EHR. In medical malpractice compensation cases, the demand for assessing the authenticity of electronic medical records is increasing, but the relevant legal guidelines are relatively lacking and scattered. Electronic medical records have the dual properties of medical records and electronic data, so the evaluation of their authenticity needs to be conducted according to two sets of regulations.

According to the relevant provisions of the Eighth National Court Conference on Civil and Commercial Trial (Civil Part) issued in 2016, if the medical record producer (usually medical institutions) cannot provide reasonable explanation for the obvious inconsistency or error in the electronic medical records, it will bear adverse consequences; and the wrong words or irregular format in the medical records will not affect the judgment of its authenticity. However, there is a large space for interpretation in the definition of concepts such as “obvious inconsistency”, “reasonable interpretation” and “format problem”.

When reviewing the authenticity of the electronic medical records, the court has the right to evaluate them by itself, or to entrust professional institutions to conduct the appraisal. Due to the lack of clear identification standards and legal basis, the authenticity identification of electronic medical records often falls into a complex situation in which both sides are difficult to clearly elaborate.

## *4.2 The Appraisal Industry Lacks Identification Standards for Electronic Medical Records*

In the field of medical injury identification, there are special guidelines such as “Medical Injury Judicial Identification Guide” (SFT 0097-2021) and “Personal Injury and Disease Causality Determination Guide” (SFT 0095-2021). In the field of handwriting identification, there is the Technical Specification for Handwriting Identification (GBT 37239-2018) as a reference standard. However, for the authentication of the

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authenticity of electronic medical record data, there is only one general specification for the Implementation of Electronic data Forensic Authentication (SFT JD0400001-2014), which is difficult to fully cover the complexity and particularity of the authentication of electronic medical record data authenticity. In addition, there is also a lack of a specific category for the authentication of electronic medical record data for the authentication of authentication institutions and authentication personnel, and usually such authentication tasks can be accepted as long as the authentication institutions have the qualification of "electronic data" authentication.

### *4.3 The Sealing System of Electronic Medical Records Lacks Legal Procedural Rules*

To seal the electronic medical records, the electronic medical records shall be jointly confirmed in the presence of the medical institution or the patient's entrusted agent, the patient or his agent, and then copied and sealed. The sealed copy of electronic medical record can be electronic version, or the printed paper version can be copied and sealed with the medical record management seal. However, the existing electronic medical record sealing system has some problems, such as the particularity of the subject, non-standard methods and unclear start-up period, which makes it difficult for the sealed electronic medical record to obtain the evidence effect directly, resulting in many difficulties in the authenticity of electronic medical record in practice.

## 5 Thinking on Perfecting the Authenticity Identification of Electronic Medical Records

The authenticity of an electronic medical record means that its content, logical structure, and background information are consistent with the original state at the time of creation. True and reliable electronic medical records should be generated by medical institutions using safe and reliable medical record system software, without illegal tampering or misuse, and all modifications can be traced and traceable. This nature is directly related to the effectiveness of the evidence of the electronic medical records in the legal process.

### *5.1 Improve Supervision Legislation of Electronic Medical Records*

In order to establish the legal evidence status of EHR in law, it is necessary to be clear at the legislative level. At present, the electronic medical records related laws and regulations mainly based on the national health committee and other institutions issued the guidance documents, including the electronic medical record system function specification (try out), ", the electronic medical record system function level classification evaluation method and standard (try out)", "based on the hospital information platform construction technology solution (version 1.0)", "electronic medical record basic architecture and data standard (try out)" and "electronic medical record application management specification (try out)", etc. Although these documents provide the basic framework for the management of EHR, they are relatively weak in legal effect and do not define the legal status and access criteria of EHR.Suggested clear the legitimacy of the legal level, it is not only to ensure its effectiveness in the judicial process, also can promote the standardization of electronic medical records management process, revised by the Supreme People's Court on the interpre-

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tation of the civil procedure law of the People's s Republic of China, clear in the relevant terms of the electronic medical records into the category of electronic data evidence, give its legal evidence.

These measures will help to improve the acceptance and utility of the EHR in judicial practice, ensuring its wide recognition in the legal process.To confirm the legal status of electronic medical records through legislation, it can provide a solid legal foundation for medical informatization, and also provide more clear and effective evidence support for the settlement of medical disputes.

### *5.2 The Authenticity of Electronic Medical Records is Verified by Digital Technology*

In medical disputes, the effectiveness of electronic medical records as evidence depends on the full use of their evidence power. In view of the current situation of electronic medical records in China, cutting-edge technologies must be adopted to ensure the authenticity and legitimacy of electronic medical records.

Electronic medical record system relies on public key infrastructure (PKI) encryption technology, which provides a solid foundation for information security. In terms of authentication, fingerprint authentication technology is widely used because of its higher security than the traditional user name and password mode. In order to ensure the integrity of data and prevent unauthorized tampering, fingerprint authentication should be combined with permission control technology.

An electronic signature has the same legal effect as a handwritten signature or seal, and any change will leave a mark.The "trusted timestamp" is issued by the authoritative timestamp service center, which determines the generation time of electronic data, effectively prevents the tampering of documents and the denial after the event, ensures the authenticity and reliability of medical information, and thus reduces the doubts of judicial and patients about electronic medical records. The combination of digital signature and time stamp can ensure the integrity and verifiability of the electronic medical record information at a specific point in time, and ensure the authenticity and relevance of the information content.

The electronic medical record system should also have the function of recording the modification traces to maintain the originality of the electronic medical records and reflect the medical review system. According to the Basic Specification for Electronic Medical Records, after each medical record modification, the system should automatically record the log, record the key information of the modification in detail, and display the modification traces and time in the printed medical time in the remarks column, further ensuring the integrity and traceability of the electronic medical record.

### *5.3 Introduce Third-Party Organizations to Ensure the Reliability of Electronic Medical Records*

Third-party preservation of electronic medical records involves delegating medical record data to a professional service provider. These service providers leverage advanced cloud storage technology and rigorous data encryption measures to secure information, while providing access control and audit monitoring systems that meet healthcare industry standards. In Norway, for example, the government has established a national electronic health record system that allows medical institutions to keep patients medical record

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data in data centers managed by the state. These centers comply with strict data protection regulations and provide high levels of data security. Through contracting and confidentiality agreements with third parties, healthcare institutions can clarify their responsibilities and obligations for data management while ensuring that service providers comply with data protection regulations such as HIPAA (Health Insurance Porability and Liability Act) or GDPR (General Data Protection Regulations). In addition, third-party preservation requires a well-established emergency response mechanism to address potential data breaches or other security threats. When implementing third-party storage, medical institutions should also obtain informed consent from patients to ensure that patients have a full understanding and trust in data storage methods and protection measures. This preservation method not only improves the credibility of electronic medical records, but also provides more reliable evidence to support for medical disputes.

### *5.4 Improve the Judicial Appraisal Mechanism of Electronic Medical Records*

In judicial practice, the identification of EHR requires not only assessing their privity and completeness, but also the joint efforts of interdisciplinary experts. This often involves information technology experts to verify the integrity of the electronic data, and experts with medical knowledge and experience in medical record management to assess the authenticity of the medical record content. In addition, the verification reports provided by the Digital Certificate Certification Authority (CA) and the Timestamp Certification Service (TSA) are also an integral part of the authentication process.

Since the experts and service agencies involved in the appraisal come from different professional fields, their collaboration mechanism in the EHR identification process needs to be clarified and improved at the institutional level. In order to ensure the efficiency and order of the appraisal work, it is suggested forming a joint appraisal team composed of multi-field experts to jointly conduct a comprehensive evaluation of the electronic medical record. Before the appraisal work begins, the responsibilities and tasks of each team member should be defined to ensure a smooth appraisal process. Facing the complex problems in the case, the team members should have a collective discussion, and form a unified appraisal opinion. During the court hearing, the appraisers shall give testimony on the part of their expertise, according to the wisdom of the team. Establish a set of standardized collaboration process to ensure that each link of electronic medical record identification can be closely linked. Through these measures, the efficiency and accuracy of electronic medical record identification can be improved, and the reliability of evidence in judicial procedures can be guaranteed.

## 6 Conclusion

To sum up, the author believes that with the continuous advancement of medical informatization, electronic medical records will become an indispensable evidence in litigation. Through the use of advanced technical support and management means, combined with a sound legal and regulatory system, we can effectively protect the authenticity of electronic medical records, reduce doctor-patient disputes, and help the court evaluate the case facts more accurately and make a fair judgment. This not only helps to protect the rights and interests of patients, but also helps to improve the service quality and reputation of medical institutions, and promotes the healthy development of the medical industry.

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