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# LEGAL STATUS ETHICAL CODES AND GUIDELINES IN CLINICAL AND MEDICAL PRACTICES

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## Abstract

It is the responsibility of the healthcare industry to adhere to a comprehensive collection of legislative frameworks, ethical standards, and guidelines that are designed to guarantee the safety of patients, the quality of treatment, and the accountability of professionals. The purpose of this abstract is to investigate the interaction of ethical requirements, professional norms, and legal status in clinical and medical procedures. Legally, clinical and medical procedures are required to comply with rules that differ from one country to another. However, these regulations always center on safeguarding patient rights, assuring informed consent, preserving confidentiality (for example, the Health Insurance Portability and Accountability Act in the United States), and preventing malpractice. The legal need to avoid negligence and to provide treatment in accordance with the generally acknowledged standard of practice is one of the boundaries that these laws impose for medical practitioners. Ethical standards, such as the Hippocratic Oath and those established by professional bodies such as the American Medical Association (AMA) or the Medical Council of India (MCI), serve as a guidance for clinicians as they carry out their moral obligations. These codes place an emphasis on such concepts as beneficence, which means working in the patient's best interest, non-maleficence, which means not causing damage, autonomy, which means respecting the choices that patients make, and justice, which means treating patients fairly. Clinical guidelines are suggestions for illness management, medical procedures, and treatment regimens that are based on evidence. These guidelines are often produced by government authorities or international organizations such as the World Health Organization (WHO). The purpose of these recommendations is to provide a practical foundation for harmonizing medical treatment by ensuring that practitioners adhere to standardized procedures that have been confirmed by modern scientific research. Ethical issues emerge when legislative frameworks and therapeutic norms are in conflict with the personal values of a practitioner, or when emerging technology, such as genetic editing or artificial intelligence in healthcare, test the established bounds of ethical conduct. As a result, it is vital to have a continuous communication between legal experts, ethicists, and medical practitioners in order to adapt to the ever shifting landscapes of healthcare. In conclusion, the legal status, ethical standards, and clinical guidelines come together to form a triangle that protects both patients and practitioners while navigating the intricacies of contemporary healthcare. This trio is responsible for maintaining the integrity of medical practice.

Keywords: Legal, Clinical, Medical, Codes

Introduction

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When it comes to maintaining the credibility of healthcare delivery, the area of clinical and medical practice functions inside a framework that is created by legal, ethical, and professional rules. Each of these criteria plays an important part in creating this framework. These components, when taken as a whole, help to secure the professional conduct of healthcare practitioners, protect the rights of patients, and promote public health. Clinical practice is supported by legal rules, which dictate what is acceptable under the law in terms of medical procedures, patient care, and practitioner obligations. These regulations serve as the structural backbone of clinical practice. A wide range of concerns, including as patient safety, informed consent, medical malpractice, and access to healthcare, are intended to be addressed by these regulations. Although they differ from nation to country, their overarching objective is to guarantee that medical practitioners adhere to the guidelines set forth by the law in order to provide treatment that is both safe and effective. For the purpose of guiding healthcare practitioners in making judgments that are ethically sound, ethical standards that are founded on philosophical ideas are utilized. These rules, like as the Hippocratic Oath, place an emphasis on the significance of compassion, competence, and respect for the autonomy of the patient. They operate as a moral compass, assisting professionals in navigating the problems of medical practice in situations when legal advice may not be sufficient or where complicated moral issues occur. Ethical problems have evolved over the past few decades to encompass developing technology, care for patients nearing the end of their lives, and the delicate balance that must be maintained between individual rights and public health interests. On the other hand, clinical guidelines include suggestions for therapy and patient management that are supported by evidence. These guidelines contribute to the standardization of care across a variety of healthcare settings and geographies. By incorporating scientific knowledge and clinical expertise, these recommendations, which were developed by expert panels and health organizations, provide healthcare practitioners with a road map to follow in the process of diagnosing, treating, and preventing illnesses. It is becoming increasingly important that legal, ethical, and clinical norms interact with one another as the sector of healthcare continues to undergo continuous change. The bounds of clinical practice are constantly being reshaped by developments in medical technology, shifts in cultural expectations, and challenges to global health. As a result, it is vital for practitioners to remain knowledgeable and comply with the most recent standards. The purpose of this study is to investigate the legal status, ethical codes, and clinical guidelines that regulate medical procedures. The research also highlights the significance of these factors in ensuring that high standards of care are maintained and in resolving the ethical difficulties and legal challenges that are now being confronted by healthcare practitioners.

### Policies, Codes, and Guidelines as "Soft Law"

On the other hand, law is a collectively defined set of standards that are supported by the state's authority to force and penalize, whereas ethics is largely based on the free behaviors of individuals, led by their own consciences. Only the broadest possible forms of instruction or ban are provided by the law in the fields of clinical practice and research, and the law is only sometimes used to enforce appropriate behavior. In the context of legal culture, the function of ethical policies, codes, and standards is not entirely clear. It is evident that they are "legal standards" or "legal norms" and that they are binding in judicial decision making when they coincide with existing legislation or when they are approved by legislators in statutes or regulations. Other examples include when they are adopted by lawmakers. Standards that are not codified in legislation or regulation, on the other hand, do not have a clear legal position, despite the fact that they may influence the behavior of health care providers. The term "soft law" has been used to refer to this collection of laws, codes, and recommendations due to the fact that its legal standing is not absolutely

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established. The topic of how a court ought to apply a "soft law" becomes considerably more complicated when the "soft law" in question pertains to professional standards of behavior rather than social norms of conduct. A court may claim that the rules, codes, and guidelines are not legally binding since they have not been incorporated into any laws or regulations. This is because they have not been adopted. Therefore, judges have the ability to reject "soft law" if the criteria that it establishes are insufficient to guarantee that reasonable care and attention are used in the execution of professional tasks. Given that judges often do not have adequate competence in the subject from which the standard originates, the counterargument is that a court ought to show deference to professional "soft law." This is because judges are not qualified to substitute their own opinions for professional opinion because they do not have sufficient expertise in the field. This piece of writing offers a comprehensive review of the legal position of "soft law" in the fields of medicine and medical research. There are several areas of clinical practice and research that entail difficulties that are both complicated and constantly evolving, yet the law does not give any advice for these issues. When it comes to this particular setting, guidance for physicians and researchers is frequently derived from sources that are neither legal or regulatory in nature. Examples of such sources include ethics policy statements, codes, and recommendations from professional or quasi-governmental organizations. The clarification of their legal status is therefore a matter that is of great importance. As a result, the focus of our study is on tracing the development of these "soft law" instruments, including how they are conceived of, how they are embraced by the professional community, and how they are eventually recognized by the judicial system. The purpose of this research is to explain how the principles and practices that regulate professional behavior might eventually carry weight as norms that are identifiable and enforceable inside the realm of law.

## Creation of Policies, Codes of Conduct, and Guidelines

There is a close connection between the history of professional self-regulation and the function that regulations and standards play in the discipline. Self-regulation may be traced back to the medieval period, when there was no central authority to mandate standards of conduct for professional groups. These professions include law and medicine, which are among the most prominent examples of self-regulation. Instead, members of the professions themselves were the ones who developed the rules that govern what constitutes acceptable conduct. Before the state began providing funding for health care systems, individual physicians served both as "professionals" and as "entrepreneurs" in the framework of the medical field. Their choices, which were based on clinical issues as well as economic considerations, were only susceptible to criticism from the medical community, and in the nineteenth century, from peer review and licensing organizations. In today's modern times, the state has emerged as the primary administrative body responsible for the regulation of professional organizations. In spite of this, the ability to exercise private control over professional behavior is still considered to be an essential component of professionalism, even by the standards of today. That is to say, however, the autonomy of the individual practitioner within this group is governed by the profession itself, despite the fact that the state has now authorized and constrained the collective power of the professional group. As a result of this, it is evident that self-regulation continues to be an essential reality for a wide variety of professional organizations, including those in the medical community.

One of the most important ways that self-regulation is accomplished in the modern era is through the formulation of practice guidelines. These guidelines are designed to set normative standards of behavior for individuals who are members of a professional community. As a result, it should not come as a surprise that the majority of these standards have typically been created by associations of certain professional

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groups. Furthermore, licensing agencies, accrediting bodies, specialty societies, governments, and private sector insurers have also participated in the formation of professional norms, albeit to a lesser level. This is in addition to the fact that these entities have been involved.5. According to LeBlang, the purpose of practice guidelines in the realm of medicine is to define the legal standard of care. By following to this standard, it is claimed that those who work in the health care industry would be able to defend themselves against charges of malpractice.

Guidelines for medical practice, on the other hand, may serve goals other than only providing practitioners in the area with legal protection. Take, for instance, the possibility that they are in existence to serve the interests of patients, research participants, or both. Guidelines and codes provide patients and subjects with information on the behavior that a professional is required to adhere to in the course of his or her work. People who would not otherwise be aware of their rights in respect to treatment or involvement in research are given the ability to exercise such rights. According to Brook, if physicians had access to recommendations that included appropriateness ratings for specific treatment techniques, they would be able to provide their patients with high-quality medical care. According to him, the medical literature has to become more explicit and directed, and he believes that this may be accomplished through the transmission of recommendations for medical practice."

One additional motivation for the formulation of recommendations might be the enhancement of the standard of medical treatment for patients. Practice guidelines ought to be concerned with six different factors, according to a study that was published in 1992 by the Institute of Medicine of the National Academy of Science in the United States of America! There is a connection between each of these and the objective of delivering superior medical care. Among them are concerns pertaining to management and rationalization, controlling costs, ensuring quality, providing access to health care, empowering patients, maintaining professional autonomy, and minimizing medical liability. Until a guideline achieves normative status, that is, until it is viewed as setting how professional practice must be carried out, it will be useless in accomplishing any of the aims outlined below since it will not be able to satisfy any of these objectives until it has been released. Following is a debate that will investigate the process by which a guideline becomes the standard within the profession, as well as the process by which it may eventually become binding within the legal community.

# **Development as a Professional Norm**

In order to establish a "authoritative reference point" that codifies what is considered acceptable practice and acknowledged developments in a profession's ever-changing field, guidelines are drafted. When experts in the area acknowledge that a standard is a "scientific principle" that dictates how they should carry out their work, only then will they consider the standard to be crucial. Therefore, when the guideline supports commonly recognized and adhered to professional practice, it becomes normative. Smith and Herbert's study, which sought to ascertain how the Canadian Task Force on Periodic Health Examination's recommendations affected the present state of preventive medicine in British Columbia, lends credence to this notion. Only suggestions that were in line with conventional wisdom and expert opinion were really implemented, according to the study. Doctors chose to stick with tried-and-true methods that were already well-respected in their field, therefore recommendations for novel maneuvers were not followed. When it comes to setting standards for one's profession, one's own conduct and customs may appear more authoritative than a set of rules put into writing. Effective guidelines may not dictate standard procedure but rather emerge as a byproduct of established norms and practices within a profession, refined and refined

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only after a practice or modification to it has gained widespread acceptance and adherence. For example, Brook thinks that a new organization should be established to work on creating and evaluating practice guidelines. According to Brook, the rules must be "either strongly considered by the profession or supported by the literature as resulting in better health" before they can be utilized, even though this autonomous group would be responsible for formulating them. Based on these findings, it seems that researchers and doctors will be providing adequate treatment provided they act in accordance with established norms of professional ethics. However, the effectiveness of practice guidelines in influencing professional standards is debatable if they only serve to formalize established practices.Guidelines may cause a shift in practice when they address something novel to the field or when they address a technique that is popular among some practitioners but unpopular with others. But in these cases, other things must accompany the formation of the rule for it to become normative. For example, recommendations need to be widely communicated so that they may be seen by experts in the field and to facilitate a discussion about whether they should impact the way professionals now work. Although rules are crucial, the social and economic incentives and disincentives that could influence medical practice are much more so. How much professionals will change their professional behavior in accordance with practice standards or codes of conduct is dependent on these criteria. Researchers Lomas found, for instance, that doctors were hesitant to change their methods once a guideline had been published. Part of the reason for this was the fear of malpractice claims that they would face for engaging in a procedure that was still considered unconventional by their peers. There were other obstacles to adopting a recommendation, such as pressure from patients and clear hospital regulations that went against the recommended approach. In most cases, these societal and economic considerations prevent a professional community from adopting standards that mandate actions that have not yet been implemented. Even among professionals, they fail to become the standard because of how ineffective they are in changing practice.

Guidelines are established and applied through an eight-step procedure, according to a research by Browman et al. According to these findings, there is a lot of support for recommendations, but they have little effect on real clinical procedures. According to the authors, this might be because doctors feel that following recommendations limits their discretion when treating patients or because guidelines don't account for the nuances of real-world situations. The feasibility of the recommended methods is another factor that might discourage the adoption of certain standards. For example, doctors might be hesitant to carry out a procedure that the guideline suggests if there is no clear evidence that it would help the patient.

### MEDICAL LAWS IN INDIA

Between 3000 and 2000 BC, the Indus urban culture emerged as the first known civilization. Henry Sigerist, a famous medical historian, thought that no ancient Asian city had better public health services than Mohenjo Daro. Whoever takes up this holy calling has been burdened with special obligations since the dawn of time. Some examples of this may be seen in the Hippocratic Oath (460 BC) and Charak's Oath (1000 BC). The Arthashastra, penned by Kautilya, provides documented proof of the state's participation and regulatory role. Since there are treatments for illnesses like pestilence and epidemics, Kautilya thought starvation was a worse disaster. He thought the king should give the doctor orders to combat epidemics with medication.3 Hammurabi, the great king of Babylon, drafted the first recorded code of rules pertaining to health practices approximately 2000 BC. Payment to physicians for adequate services was one of several areas regulated by these rules, which are also known as the code of Hammurabi. The laws were quite harsh, and the punishments for damaging treatments were severe. There was a real possibility of death for doctors

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whose treatments turned out to be incorrect. The first medical practice code was this. Hippocrates, a Greek physician, established the first rule of medical ethics, the Hippocratic oath, almost two millennia ago, in the fifth century BC. His legacy as the "Father of Western medicine" lives on in modern times. For generations, the Hippocratic oath has served as a code of ethics for the medical profession. The World Health Organization (WHO) drew extensively on the ancient Hippocratic Oath when it drafted the Declaration of Geneva, an updated version of the oath that has since been adopted as the global rule of medical ethics, following World War II. The Ashoka dynasty (270 BC) was a time of law and public works, healthcare, and education. All around his empire, he set up hospitals that the state would pay for medical care for.4 The Charaka Samhita provides a detailed description of ethics, and the Ayurvedic doctors of ancient India had a clearly defined code of conduct when it came to medicine.5 Doctors, barbers, and surgeons were brought in by the colonial authorities. As the medication gained renown in England in the middle of the nineteenth century, it gradually began to have an effect in India as well. Colonial health policy in India was primarily influenced by worries about the soldiers and civilian population of Europe after 1857.6 The development of a regulatory framework for medical professionals was another step in the process of healthcare system building. There had to be rules and restrictions put in place for the doctors and surgeons who were brought in by the East India Company and the British government after 1857. According to 'A history of Indian medical services, 1600-1913' written by Lt. Colonel DG. Crawford, these doctors were subjected to sanctions (including deportation) for various infractions, including insubordination, malpractice, and lack of discipline. Additionally, it details the rules that the East India set the hospitals built. Company up for that thev In 1857, a legislation was passed in England that established the General Medical Council. British doctors working in India were required to register with the GMC and were subject to its disciplinary regulations. The need to establish regulations for Indian medical schools arose in response to the rising tide of medical graduates. The coroner's statute applicable to Bombay and Calcutta was adopted in 1871 by the colonial administration for several purposes, including criminal processes. It outlined the responsibilities of doctors and other medical personnel during autopsies and inquests. It took a long time, nevertheless, for the legislation for indigenous medical councils to be passed. Also at this time, legislation was passed to separate the poor from the general population and provide them with medical care in the event of an epidemic, among other things. While a new legislation removed and replaced the Lepers Act of 1898 in the early 1980s, the Epidemic Disease Act of 1807 remains in effect with revisions. The medical council was created in 1880 by the Grant Medical College Society, which approved the Bombay Medical Act. The appointment of a registrar, the preservation of names in the register, and the imposition of penalties for violations were all part of the original rule draft for this act. Bombay Medical Act was passed in 1912 by the Bombay Presidency. Subsequently, additional provinces passed their own medical legislation. It was in 1914 that two acts were passed, one in Bengal and one in Madras, pertaining to medical registration. After these provincial statutes, in 1916, the Indian Legislative Council passed and the Governor General authorized the Indian Medical Degree Act. Following the passage of the Indian Medical Council Act in 1933, a statutory body for modern medicine practitioners at the national level was established: the Medical Council of India. In 1938, the Bombay Medical Practioner Act was enacted, marking the first official acknowledgment and registration of Indian medical systems.

#### **Post 1947 Developments**

In 1947, the country gained its independence, which marked the beginning of a new era in the development of organized health care services, which resulted in increased entitlements for the people. In addition to

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this, the state also began the process of enacting new laws, modifying the laws that had been established by the colonial government, and developing case laws in order to strengthen the rights of the people and to expand their access to health care. India was faced with the challenge of establishing the physical and institutional infrastructure necessary for the rapid growth or modernization of the country during the period of time that followed the country's independence and the first few years of planning. Over the course of time, the Indian parliament has enacted a significant number of legislation and acts that aim to improve the delivery of healthcare in the country.

## **Prerequisites of Medical Practice**

An appropriately qualified medical practitioner, such as a physician, has the right to seek to practice medicine, surgery, and dentistry. In order to do so, he must first register himself with the medical council of the state in which he resides and then follow the procedure that is defined by the medical act of the state. Doctors who have been found guilty of notorious behavior in any professional regard or who have been convicted by any court for any nonbailable offense are subject to the authority of the state medical council, which has the authority to issue warnings, refuse to register, or delete their names from the registry record. A further authority that the state medical council possesses is the authority to re-enter the name of the physician into the registry. The Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulation 2002 includes a clause that states the provisions related offenses and professional misconduct that may be brought before the relevant medical council (state/medical Council of India). These provisions are listed in the regulation. Unless the individual in question has been provided with the chance to be heard either in person or through an advocate, it is impossible to pursue any kind of action against a medical practitioner.

## **Emergency Healthcare and Laws**

A resounding declaration made by the Supreme Court of the United States was that the fundamental right to life encompassed the ability to get medical attention in an emergency situation. This significant occasion was highlighted by the landmark verdict that was handed down by the Supreme Court of India in 1989 in the case of Parmanand Katara v. Union of India. As a result of this particular incident, a scooterist who had suffered severe injuries as a result of a road accident was denied admittance to the nearby hospital on the grounds that the hospital did not possess the necessary expertise to deal with medicolegal issues. The Supreme Court of the United States, in its decision, stated that the responsibility of medical practitioners to offer treatment in instances of crises took precedence over the professional freedom to deny patients. The court made a categorical statement that "Article 21 of the Constitution casts the obligation on the state to preserve life." This was in accordance with the right to emergency care, which is considered to be a basic right under Article 21 (the fundamental right to life). It is interesting to note that the Supreme Court went on to state that not just government hospitals but also "every doctor, whether at a government hospital or otherwise, has the professional obligation to extend his or her service with due expertise for the purpose of protecting life." In a different case (Paschim Banga Khet Majdoor Samity vs. State of West Bengal, Supreme Court, 1996), a person who had suffered brain injuries as a result of a train accident was denied treatment at a number of hospitals on the grounds that they did not have the necessary equipment and infrastructure to offer treatment. The Supreme Court of the United States, in this particular case, further developed the right to emergency treatment and went on to state that a violation of a person's right to life, as guaranteed by Article 21, occurs when a government hospital fails to provide timely medical treatment to a person who is in need of such treatment.

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# Conclusion

When it comes to providing healthcare that is not only safe and effective but also compassionate, the legal status, ethical standards, and clinical guidelines that regulate medical procedures are essential components. The combination of these components results in a structure that provides assistance to medical professionals in the process of making decisions on a daily basis, while also protecting the rights and wellbeing of patients. It is essential that these legal, ethical, and clinical frameworks be evaluated and updated on a regular basis in order to adequately address the difficulties that are presented by contemporary medicine. This is because the area of healthcare is continuously undergoing change, particularly in light of the fast growth of medical technology. For the purpose of ensuring that healthcare practitioners continue to offer high-quality treatment in a way that is both morally and legally sound, it is vital for them to comprehend and implement these frameworks.

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