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Law, Ethics, and Safety



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Table of Contents

Medical Ethics	4
Consent	5
Infrared Lamps and Burns	7
Sharing Medical Information	10
Scope of Practice	14
Examples of State Scope of Practice Rules	15
Equitable Access Principle	18
Sun Szu-Miao	18
Single-Use Needles, Law & Ethics	21
California & Florida Single-Use	21
Confucianism	22
Hippocratic Oath	23
Taoism & Buddhism	24
Recent Ethics Developments	25
Healthcare, Law, and Ethics Summary	27
Biomedical Waste & Safety	29

Medical Ethics

Ethics are moral principles that act as guidelines for behavior. They act as a guiding philosophy, impart moral importance, and help discern right from wrong. Although ethics correlate to legality, ethical obligations are often greater than what is legally required. Conversely, simply because something is legal does not necessarily make it ethical. The following is an excerpt from the American Medical Association's website on the topic of the relation of law and ethics:

Ethical values and legal principles are usually closely related, but ethical obligations typically exceed legal duties. In some cases, the law mandates unethical conduct. In general, when physicians believe a law is unjust, they should work to change the law. In exceptional circumstances of unjust laws, ethical responsibilities should supersede legal obligations.

The fact that a physician charged with allegedly illegal conduct is acquitted or exonerated in civil or criminal proceedings does not necessarily mean that the physician acted ethically.¹

While it is ethical to practice acupuncture, it is not legal to practice it in many jurisdictions and settings. Likewise, there are acupuncture procedures that are ethical to perform but lack legal support in state scope of practice definitions. The same is true for herbal medicines. Herbs may be illegal that are safe and effective. In all cases, acupuncturists must abide by the law, but ethics imparts the responsibility of working towards changing the laws for the betterment of humanity.

Law and medical ethics help to ensure the safety, dignity, and rights of patients, while also guiding healthcare professionals in their duties. Medical ethics, often based on principles such as autonomy, beneficence, non-maleficence, and justice, helps doctors navigate complex moral situations. Law, on the other hand, provides a structured framework that defines the legal boundaries of medical practice, protecting both patients and practitioners from harm.

¹ [ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion102.page?](https://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion102.page?) 1-1-16.

An important intersection of law and medical ethics is informed consent, where patients must fully understand and agree to the risks, benefits, and alternatives of a treatment before it proceeds. Failure to obtain informed consent can lead to legal repercussions, including malpractice claims, while ethically, it can compromise patient autonomy and trust. Both law and ethics work together to ensure that medical practice is conducted in a manner that respects the individual rights of patients and upholds professional integrity.

Consent

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, sets national standards for healthcare related electronic health care transactions and code sets, unique health identifiers, and security. Patient records and information of licensed acupuncturists fall under the purview of HIPAA. HIPAA covers privacy and not consent.

Consent to treatment relates to the patient intake information form signed prior to the first office visit or treatment. A consent to treat signature is required and is governed by state or regional regulations, not HIPAA. HIPAA covers the privacy and security of patient information but is unrelated to the requirement for a consent to treat form. HIPAA governs the privacy and security of the information once it is gathered. HHS notes:

How does the HIPAA Privacy Rule change the laws concerning consent for treatment?

Answer:

The Privacy Rule relates to uses and disclosures of protected health information, not to whether a patient consents to the health care itself. As such, the Privacy Rule does not affect informed consent for treatment, which is addressed by State law.

Consent to treat form requirements vary from state to state and malpractice insurance carriers may require additional information or an arbitration form. A typical consent to treat form includes:

- **patient's name and signature**
- **address**
- **today's date**
- **date of birth**
- **personal contact information**
- **emergency contact information**
- **name of treating physician**
- **medical history including allergies and medications**

Auto personal injury and workers compensation insurance companies may require a social security number (SSN) for reimbursement because the SSN is used as part of the patient's insurance identification number for the carrier. Consent forms usually inform the patient concerning possible adverse effects and warnings associated with treatment and may look like the following:

Sometimes, after receiving an acupuncture treatment, you may feel a little bit light-headed. If that is the case, please sit for a while in the reception area.

You may get a small hematoma (a small bruise under the skin) after an acupuncture needle is removed.

Medicinal herbs are intended only for the person for which they are given to.

Although not required in all areas, an important question for the intake form is: "Is there any chance that you are pregnant?"

The patient's signature is always required and usually follows a statement similar to the following: "My signature authorizes (name of acupuncturist) to treat me with acupuncture and Chinese medicinal herbs within the licensure granted by the (state medical board name)." HIPAA pertains to the safeguarding of this information once gathered but HIPAA does not require obtaining the information.

Infrared Lamps and Burns

Malpractice insurance companies note that many law suits against acupuncturists are preventable. Uniformly, insurance carriers voice a concern regarding burns. Heat lamps and moxibustion are the primary concern.

The Medical Insurance Exchange of California (MIEC) reports that 17% of all claims against acupuncturists in 2005 – 2014 were for patients sustaining a burn injury. Out of the 17% total, 11% of burns were caused by infrared heat lamps, 4% due to indirect moxibustion, and 2% were due to hot stone massage.² The MIEC recommends that placement of a heat lamp should be such that, in case of a malfunction, the lamp will not come into contact with the patient.

If a burn occurs, it is legally important that the patient had been aware of this possibility. This goes to the issue of informed consent. The American Acupuncture Council includes the following informed consent item in their recommended *Acupuncture Informed Consent to Treat* form:

I have been informed that acupuncture is a generally safe method of treatment, but that it may have some side effects, including bruising, numbness or tingling near the needling sites that may last a few days, and dizziness or fainting. **Burns and/or scarring are a potential risk of moxibustion and cupping, or when treatment involves the use of heat lamps.** Bruising is a common side effect of cupping.³

Direct moxa is expressly forbidden by law in some US states, while indirect moxa is allowed in most states and countries. Check your scope of practice regulations or confer with your state acupuncture board to find out what types of moxibustion are legal in your state. Indirect moxa may leave scars or welts. Practitioners are advised to ensure that no scarring or welts occur to avoid legal ramifications. Although scarring moxibustion is historically used, in today's legal environment, it is either inappropriate or illegal in

2. MIEC, Point of Exchange, July 2015. Burn injury claims resulting from indirect moxibustion and TDP lamps.

3. AAC-FED, A2004. OPTIONAL Arbitration Information Packet. American Acupuncture Council.

most regions. Heat shields are important at the base of a needle when moxa is attached to the handle.

TDP (Teding Diancibo Pu) heat lamps and other types of infrared lamps must be used with care. One of the most important concerns is awareness of patients with numbness or any impairment of the sensory capacity for heat. For example, diabetics often have decreased sensitivity in their extremities. These patients may be unable to tell the acupuncturist that the lamp is too hot because they are unable to feel the area receiving the heat.

Consider some of the following issues with heat lamps:

- **unstable base or stand**
- **overextended heat lamp adjustment arm**
- **inadequate screen (protective guard) between the heating element or bulb and the patient**
- **a power cord that may be tripped over**
- **heat source too close to patient's skin**

The Council of Colleges of Acupuncture and Oriental Medicine (CCAOM) notes “It is imperative that a TDP lamp be monitored carefully when in use and that unexpected movements of the heating element be prevented. Some lamps may slowly lower during the course of a treatment, resulting in a burn over the area being warmed. Mechanical failure of the heat lamp itself may occur during treatment allowing the arm and heating element to rapidly descend near or onto the patient's skin.”⁴

One of the best legal protections in the case of an accident or injury in an acupuncturist clinic is the acupuncturist's good relations with the patient. Insurance companies note that, even in the case of severe burns, cases have a higher tendency to settle out of court when there is a good relationship between the acupuncturist and the patient.

4. Council of Colleges of Acupuncture and Oriental Medicine (CCAOM), 2014.

If an accident or injury occurs, take appropriate steps to provide care to the patient to help remedy the medical issue. The Council of Colleges of Acupuncture and Oriental Medicine recommends, “If the burn is a very small, first-degree burn, provide treatment such as cool water, sterile gauze and over-the-counter burn creams. If the burn is severe, or there is concern with infection, refer the patient to a physician.”⁵

Steps to take:

- for minor burns: apply a burn cream, cool water, or other appropriate treatments to alleviate inflammation and skin damage
- refer to an appropriate outside medical source when needed
- express genuine concern and care for the patient’s health and well-being
- document the issue
- document follow-ups with patient on their health status
- advise the patient on steps they may take to relieve a burn



5. Council of Colleges of Acupuncture and Oriental Medicine (CCAOM), 2014.

Sharing Medical Information

Compassionate acknowledgement that an illness may be terminal is consistent with Chinese medicine history.⁶ In the book Medical Ethics in China: A Transcultural Interpretation, Jing-Bao Nie writes:

Besides Yi He and Yi Huan, other founding figures of Chinese medicine include Qin Yueren (fl. c. 500 BCE, popularly known as Bian Que, dubbed the “father of medicine” by some historians), Zhang Zhongjing (c. second century AD, renowned as the “sage of medicine”) and Hua Tuo (c. second century AD known as the “father of surgery”). Without exception, their practice was to tell their patients the truth when their illness was diagnosed as terminal. There are no records of any of these great Chinese physicians ever recommending that a doctor should conceal such information from his patients. Zhongjian once predicted that a patient would die in twenty years’ time, and prescribed medicine to prevent it. However, despite the doctor’s warning, the patient refused to take the prescribed medication and died exactly as Zhang had foretold.

In the case of a non-compliant patient, an attempt to work with the patient, care givers, or family to encourage compliance with health care advice for the safety of the patient is an ethical choice to advocate for the patient even when they may resist beneficial care. There are other historical examples wherein the attending physician communicated the news of a terminal prognosis truthfully, but may have told the care givers and the patient directly:

In another case, Cang Gong’s language was evasive. He first told his patient: “You are suffering from such a grave illness that I should not speak about it (Jun zi bing’e, buke yan ye).” He then disclosed some further medical information and told the patient’s brother that he had just eight days to live. In another case, although the truth about a terminal illness was delivered in straightforward terms, it is unclear whether this information was given to the patient or to a third party. In two other cases where the patients were respectively a maid and male servant, it was their masters, not the patients themselves, who were directly informed.⁷

6. Nie, Jing-Bao. *Medical ethics in China: A transcultural interpretation*. Routledge, 2013.

7. Nie, Jing-Bao. *Medical ethics in China: A transcultural interpretation*. Routledge, 2013, pg 105.

Care must be given when sharing medical information. Privacy laws prevent sharing medical information to third parties without consent of the patient. Therefore, some of Cang Gong's actions are not legally permissible in today's environment without prior consent. However, sharing important medical information is legal for the purposes of treatment. Under the Privacy Rule, the HHS (U.S. Department of Health and Human Services) notes that health care providers may share patient information for treatment purposes:

Does the HIPAA (Health Insurance Portability and Accountability Act of 1996) Privacy Rule permit doctors, nurses, and other health care providers to share patient health information for treatment purposes without the patient's authorization?

Answer:

Yes. The Privacy Rule allows those doctors, nurses, hospitals, laboratory technicians, and other health care providers that are covered entities to use or disclose protected health information, such as X-rays, laboratory and pathology reports, diagnoses, and other medical information for treatment purposes without the patient's authorization. This includes sharing the information to consult with other providers, including providers who are not covered entities, to treat a different patient, or to refer the patient.

This statement on sharing patient health information is taken from the Code of Federal Regulations, Title 45, Public Welfare, 164.506 (45 CFR 164.506). The following is the federal code:

Uses and disclosures to carry out treatment, payment, or health care operations.

(a) Standard: Permitted uses and disclosures. Except with respect to uses or disclosures that require an authorization under § 164.508(a)(2) and (3), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.

(b) Standard: Consent for uses and disclosures permitted. (1) A covered entity may obtain consent of the individual to use or disclose protected health information to carry out treatment, payment, or health care operations.

(2) Consent, under paragraph (b) of this section, shall not be effective to permit a use or disclosure of protected health information when an authorization, under § 164.508, is required or when another condition must be met for such use or disclosure to be permissible under this subpart.

(c) Implementation specifications: Treatment, payment, or health care operations.

(1) A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations.

(2) A covered entity may disclose protected health information for treatment activities of a health care provider.

(3) A covered entity may disclose protected health information to another covered entity or a health care provider for the payment activities of the entity that receives the information.

(4) A covered entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is:

(i) For a purpose listed in paragraph (1) or (2) of the definition of health care operations; or

(ii) For the purpose of health care fraud and abuse detection or compliance.

(5) A covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to another covered entity that participates in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

This code allows licensed acupuncturists to work with other licensed health care providers and share patient information for purposes of treatment. The same applies to working with specialists. The HHS notes:

Does a physician need a patient's written authorization to send a copy of the patient's medical record to a specialist or other health care provider who will treat the patient?

Answer:

No. The HIPAA Privacy Rule permits a health care provider to disclose protected health information about an individual, without the individual's authorization, to another health care provider for that provider's treatment of the individual.

Can a physician's office fax patient medical information to another physician's office?

Answer:

The HIPAA Privacy Rule permits physicians to disclose protected health information to another health care provider for treatment purposes. This can be done by fax or by other means. Covered entities must have in place reasonable and appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information that is disclosed using a fax machine. Examples of measures that could be reasonable and appropriate in such a situation include the sender confirming that the fax number to be used is in fact the correct one for the other physician's office, and placing the fax machine in a secure location to prevent unauthorized access to the information.

Scope of Practice

Legal and ethical considerations may conflict. Legally, the scope of practice and state laws may prevent an acupuncturist from using procedures and implements consistent with traditional implementation of acupuncture and herbal medicine. Herbs may not be lawful in some areas; certain types of acupuncture needles or manual acupuncture techniques may be illegal in other areas. The acupuncturist is challenged to work within the legally defined scope of practice.

There is also a gray area. The scope of practice or regional laws may not prohibit a treatment modality or technique but also do not explicitly allow for its use. Magnet therapy, laser acupuncture, bleeding techniques, etc... may not be prohibited or explicitly allowed. As result, acupuncturists are advised to work strictly within their scope of practice and check with their state boards concerning undefined procedures and techniques.

At all times, stay within the boundaries of the law and the scope of practice. That is the legal standard. The ethical standard is to contribute towards changing the law such that appropriate modalities and techniques are included in the scope of practice. The American Medical Association notes:

In general, when physicians believe a law is unjust, they should work to change the law.⁸

At the Healthcare Medicine Institute, our team of translators and writers provides a free news service that covers up-to-date acupuncture and herbal medicine research. This helps to create public awareness and has contributed to changes in legislation. To access this service, visit the news section of HealthCMI.com to see our latest publications. Contributions to research and political outreach are two methods to ensure access to appropriate traditional medicine including acupuncture and herbs.

⁸ <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion102.page>. 1-1-16.

Examples of State Scope of Practice Rules

The following is a comparison of Florida and California to help get a general understanding of scope of practice on a national scale.

The following is the rule for the State of Florida:

457.102 Definitions.—As used in this chapter:

- (1) "Acupuncture" means a form of primary health care, based on traditional Chinese medical concepts and modern oriental medical techniques, that employs acupuncture diagnosis and treatment, as well as adjunctive therapies and diagnostic techniques, for the promotion, maintenance, and restoration of health and the prevention of disease. Acupuncture shall include, but not be limited to, the insertion of acupuncture needles and the application of moxibustion to specific areas of the human body and the use of electroacupuncture, Qi Gong, oriental massage, herbal therapy, dietary guidelines, and other adjunctive therapies, as defined by board rule.
- (2) "Acupuncturist" means any person licensed as provided in this chapter to practice acupuncture as a primary health care provider.
- (3) "Board" means the Board of Acupuncture.
- (4) "License" means the document of authorization issued by the department for a person to engage in the practice of acupuncture.
- (5) "Department" means the Department of Health.
- (6) "Oriental medicine" means the use of acupuncture, electroacupuncture, Qi Gong, oriental massage, herbal therapy, dietary guidelines, and other adjunctive therapies.
- (7) "Prescriptive rights" means the prescription, administration, and use of needles and devices, restricted devices, and prescription devices that are used in the practice of acupuncture and oriental medicine.

The following are from the State of California laws and regulations:

4927. As used in this chapter, unless the context otherwise requires:

- (a) "Board" means the Acupuncture "Board".
- (b) "Person" means any individual, organization, or corporate body, except that only individuals may be licensed under this chapter.
- (c) "Acupuncturist" means an individual to whom a license has been

issued to practice acupuncture pursuant to this chapter, which is in effect and is not suspended or revoked.

(d) "Acupuncture" means the stimulation of a certain point or points on or near the surface of the body by the insertion of needles to prevent or modify the perception of pain or to normalize physiological functions, including pain control, for the treatment of certain diseases or dysfunctions of the body and includes the techniques of electroacupuncture, cupping, and moxibustion.

4937. An acupuncturist's license authorizes the holder thereof:

(a) To engage in the practice of acupuncture.

(b) To perform or prescribe the use of Asian massage, acupressure, breathing techniques, exercise, heat, cold, magnets, nutrition, diet, herbs, plant, animal, and mineral products, and dietary supplements to promote, maintain, and restore health. Nothing in this section prohibits any person who does not possess an acupuncturist's license or another license as a healing arts practitioner from performing, or prescribing the use of any modality listed in this subdivision.

(c) For purposes of this section, a "magnet" means a mineral or metal that produces a magnetic field without the application of an electric current.

(d) For purposes of this section, "plant, animal, and mineral products" means naturally occurring substances of plant, animal, or mineral origin, except that it does not include synthetic compounds, controlled substances or dangerous drugs as defined in Sections 4021 and 4022, or a controlled substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code.

(e) For purposes of this section, "dietary supplement" has the same meaning as defined in subsection (ff) of Section 321 of Title 21 of the United States Code, except that dietary supplement does not include controlled substances or dangerous drugs as defined in Section 4021 or 4022, or a controlled substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code.

4938. The board shall issue a license to practice acupuncture to

any person who makes an application and meets the following requirements:

- (a) Is at least 18 years of age.

This last part is an interesting contrast. In California, an acupuncturist must be at least 18 years of age but in Florida the minimum age is 21. The following is the State of Florida rule:

57.105 Licensure qualifications and fees.—

(1) It is unlawful for any person to practice acupuncture in this state unless such person has been licensed by the board, is in a board-approved course of study, or is otherwise exempted by this chapter.

(2) A person may become licensed to practice acupuncture if the person applies to the department and:

- (a) Is 21 years of age or older, has good moral character, and has the ability to communicate in English, which is demonstrated by having passed the national written examination in English or, if such examination was passed in a foreign language, by also having passed a nationally recognized English proficiency examination;

This last section (57.105, 2, a) represents another emerging trend. English is slowly becoming a required language in the USA on a national scale. There has been a phasing out of Korean, Japanese and Chinese language acupuncture examinations for licensure nationally. This is controversial in that expert practitioners from China and other Asian countries may not be able to obtain acupuncture licenses in the USA without significant study of the English language. The proponents of this requirement suggest that this will reduce medical errors. In Florida, the English language requirement is written into law.

Equitable Access Principle

Patients deserve fair and equitable access to healthcare and quality treatments. In this respect, patients must be treated with equal respect. The concept that patients deserve equal access to care has historical roots in Chinese medicine:

Chen Shih-kung (AD1605) also presented the similar idea of treating high or low, rich or poor equally. He particularly mentioned that prostitutes should be treated in the same way as daughters from a good family, which entails both equality and respect. Moreover: "Medicine should be given free to the poor. Extra financial help should be extended to the destitute patients; if possible. Without food, medicine alone cannot relieve the distress of a patient."⁹

Sun Szu-miao wrote about nondiscrimination:

If someone seeks help because of illness or on the ground of another difficulty, [a great physician] should not pay attention to status, wealth or age, neither should he question whether the particular person is attractive or unattractive, whether he is an enemy or a friend, whether he is Chinese or a foreigner, or finally, whether he is uneducated or educated. He should meet everyone on equal ground.¹⁰

Sun Szu-Miao

Sun Szu-Miao (孫思邈, 541–682 CE) is one of the most celebrated figures in traditional Chinese medicine (TCM). He was a renowned physician, Taoist, and pharmacologist during the Sui and Tang dynasties, often referred to as the “King of Medicine” (药王). His contributions to medical theory, ethics, and practice had a profound influence on the development of Chinese medicine.

Key Contributions:

⁹ Tsai, D. F. "Ancient Chinese medical ethics and the four principles of biomedical ethics." *Journal of medical ethics* 25, no. 4 (1999): 315-321.

¹⁰ Tsai, D. F. "Ancient Chinese medical ethics and the four principles of biomedical ethics." *Journal of medical ethics* 25, no. 4 (1999): 315-321.

1. **“Prescriptions Worth a Thousand Gold Pieces” (千金方):** Sun Szu-Miao authored two important medical texts: *Qian Jin Yao Fang* (Essential Prescriptions Worth a Thousand Pieces of Gold) and *Qian Jin Yi Fang* (Supplement to the Essential Prescriptions). These texts cover a wide range of topics, including medical theory, treatment for various ailments, herbal medicine, acupuncture, surgery, and even gynecology. They remain influential in Chinese medicine today.

2. **Emphasis on Preventive Medicine:** Sun was a strong advocate for preventive care. He believed in maintaining health through a balanced lifestyle, proper diet, and moderate behavior, which are principles that resonate with modern holistic approaches to health.

3. **Ethics in Medicine:** Sun Szu-Miao was also known for his views on medical ethics. His famous passage, “The Heart of Medicine” (大医精诚), expresses the idea that physicians should treat all patients with compassion and integrity, regardless of their social status, wealth, or the nature of their illness. His ethical guidelines are still referenced in discussions on medical professionalism.

4. **Herbal Medicine:** He was instrumental in compiling and documenting various herbs and their medicinal properties. His work contributed to the foundation of traditional Chinese pharmacology.

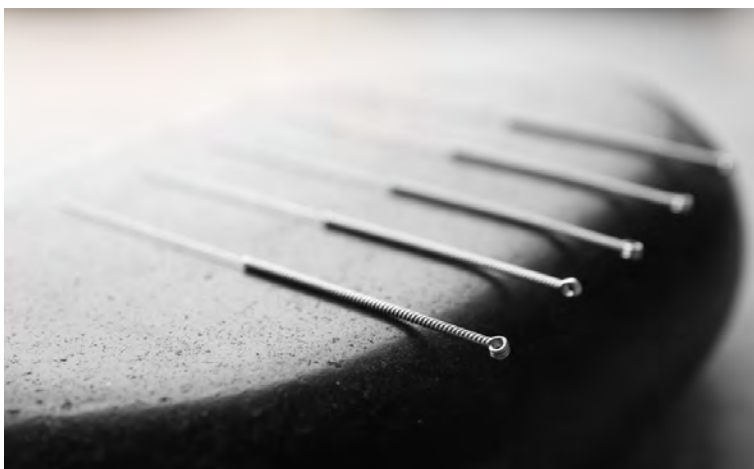
Sun Szu-Miao’s integration of medicine, Taoist philosophy, and ethics not only advanced Chinese medical practices but also laid a moral and practical foundation that has endured for centuries. His legacy continues to influence both traditional Chinese medicine practitioners and modern healthcare professionals interested in holistic and ethical approaches to medicine.

Sun Simiao wrote a treatise entitled “On the Absolute Sincerity of Great Physicians.” This was a section of the work entitled *The Important Prescription Worth a Thousand Pieces of Gold*. The treatise “requires the physician to develop first a sense of compassion and piety, and then to

make a commitment to try to save every living creature, to treat every patient on equal grounds, and to avoid seeking wealth because of his expertise.”¹¹

Sun Simiao commented on relations with colleagues, “it is inappropriate to emphasize one’s reputation, to belittle the rest of the physicians and to praise only one’s own virtue.”¹² He also wrote:

...a Great Physician should possess a clear mind, in order to look at himself; he should make a dignified appearance, neither luminous nor somber. It is his duty to reduce diseases and to diagnose sufferings and for this purpose to examine carefully the external indications and the symptoms appearing in the pulse. He has to include thereby all the details and should not overlook anything. In the decision over the subsequent treatment with acupuncture or with medicaments nothing should occur that is contrary to regulations. The saying goes: “In case of a disease one has to help quickly,” yet it is nevertheless indispensable to acquaint oneself fully with the particular situation so that there remain no doubts. It is important that the examination be carried out with perseverance. Wherever someone’s life is at stake, one should neither act hastily nor rely on one’s own superiority and ability, and least of all keep one’s own reputation in mind. This would not correspond to the demands of humaneness!¹³



11. Veatch, Robert M. Cross-cultural perspectives in medical ethics. Jones & Bartlett Learning, p 320-321, 2000.

12. Veatch, Robert M. Cross-cultural perspectives in medical ethics. Jones & Bartlett Learning, 2000.

13. Veatch, Robert M. Cross-cultural perspectives in medical ethics. Jones & Bartlett Learning, p 314, 2000.

Single-Use Needles, Law & Ethics

Globally, some regions allow reusable needles that have been sterilized with autoclave equipment. However, many areas allow only single-use acupuncture needles. For example, in the United States, California only allows for single-use needles. The ethical standard for use of autoclaves has been met only if the process ensures complete sterilization; regardless, this standard is superseded by law. In addition, many acupuncturist malpractice insurance and health insurance policies forbid the use of reusable needles. Let's take a look at two examples:

California & Florida Single-Use

The State of California specifically prohibits the reuse of acupuncture needles:

1399.454. Single Use Needles.

An acupuncturist shall use needles labeled for single use only that meet the requirements of federal regulations 21 CFR Part 880.5580 (61 FR 64617, December 6, 1996). It shall constitute unprofessional conduct for an acupuncturist to use a needle more than once.

This is a general trend in laws and regulations for filiform needles. The State of Florida has a similar provision:

457.1085 Infection control.—Prior to November 1, 1986, the board shall adopt rules relating to the prevention of infection, the safe disposal of any potentially infectious materials, and other requirements to protect the health, safety, and welfare of the public. Beginning October 1, 1997, all acupuncture needles that are to be used on a patient must be sterile and disposable, and each needle may be used only once.



Confucianism

Basic principles of medial ethics have their their roots in ancient traditional Chinese medicine. Daqing Zhang and Zhifan Cheng note in "Medicine Is a Humane Art: The Basic Principles of Professional Ethics in Chinese Medicine":

The value system of medical ethics in China has a long tradition that can be traced back to ancient times. Those values are reflected in the (Confucian) precept that "medicine is a humane art." That is, medicine is not only a means to save people's lives, but also a moral commitment to love people and free them from suffering through personal caring and medical treatment. Although this precept has been well accepted as the basic principle of professional ethics as a general principle that emphasizes doctors' self-accomplishment and self-restraint, there has never been a universally accepted professional code and binding principles in Chinese medicine comparable to the *Hippocratic Oath* in western.¹⁴



Confucian Temple (Taichung, Taiwan)

¹⁴Zhang, Daqing, and Zhifan Cheng. "Medicine is a humane art the basic principles of professional ethics in Chinese medicine." *The Hastings Center Report* 30, no. 4 (2000): S8-S12.

Hippocratic Oath

Hippocrates (460–375 BCE) was an ancient Greek physician. Authorship of the *Hippocratic Oath*, an ancient ethical code, is attributed to Hippocrates. To this day, classical and contemporary versions of the *Hippocratic Oath* are included in some medical school graduation ceremonies. By today's standards, there are several aspects of the *Hippocratic Oath* that are considered significantly controversial. The following is a translation of the *Hippocratic Oath* from the original Greek by Francis Adams in 1849:

I swear by Apollo the physician, and Aesculapius, and Health, and All-heal, and all the gods and goddesses, that, according to my ability and judgment, I will keep this Oath and this stipulation—to reckon him who taught me this Art equally dear to me as my parents, to share my substance with him, and relieve his necessities if required; to look upon his offspring in the same footing as my own brothers, and to teach them this Art, if they shall wish to learn it, without fee or stipulation; and that by precept, lecture, and every other mode of instruction, I will impart a knowledge of the Art to my own sons, and those of my teachers, and to disciples bound by a stipulation and oath according to the law of medicine, but to none others.

I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous. I will give no deadly medicine to any one if asked, nor suggest any such counsel; and in like manner I will not give to a woman a pessary to produce abortion. With purity and with holiness I will pass my life and practice my Art.

I will not cut persons laboring under the stone, but will leave this to be done by men who are practitioners of this work. Into whatever houses I enter, I will go into them for the benefit of the sick, and will abstain from every voluntary act of mischief and corruption; and, further from the seduction of females or males, of freemen and slaves. Whatever, in connection with my professional practice or not, in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret.

While I continue to keep this Oath unviolated, may it be granted to me to enjoy life and the practice of the art, respected by all men, in all times! But should I trespass and violate this Oath, may the reverse be my lot!

Taoism & Buddhism

In addition to Confucianism, Chinese medicine ethics has its roots in both Taoist and Buddhist values:

Taoism and Buddhism also influenced the development of medical ethics in China, themselves vigorously promoting the practice of medicine as a means of doing good. Taoism favors life and resents death. It regards being alive as the happiest thing and pursues immortality. Taoists pursue long life in either of two ways: by taking special medicines made from plants, animals, or minerals and by doing good deeds that benefit others. Five commandments are at the heart of Taoist religious codes. A Taoist is forbidden to kill any living thing, eat any meat or drink any alcohol, behave dishonestly, steal, or be sexually promiscuous. Central values in Taoism include loyalty, filial piety, politeness, trust, and humanity.

Buddhism is also a very important thread in the fabric of traditional Chinese medical ethics. To alleviate suffering and transcend the cycle of fate (karma) and rebirth, many Buddhists practiced good deeds by means of practicing medicine. Among China's early physicians were many well-known Buddhist monks, like Jianzhen of the Tang Dynasty who was not only a famous monk but also an outstanding doctor of great attainments.¹⁵



Taoist Temple Garden at Weibao Mountain (Yunnan, China)

¹⁵Zhang, Daqing, and Zhifan Cheng. "Medicine is a humane art the basic principles of professional ethics in Chinese medicine." *The Hastings Center Report* 30, no. 4 (2000): S8-S12.

Recent Ethics Developments

Recent discussions and developments in medical ethics have introduced several new ideas and challenges, especially in light of advances in technology, shifting societal values, and emerging global health issues. Some of the most prominent new ideas in medical ethics include:

- 1. AI and Medical Decision-Making:** The integration of artificial intelligence (AI) in healthcare raises ethical questions about the extent to which machines should participate in decision-making processes. AI has the potential to improve diagnostics, predict outcomes, and personalize treatment. However, issues around accountability, consent, transparency, and bias in AI-driven healthcare systems are central concerns. Medical ethicists are exploring how to balance the efficiency of AI with the need for human oversight, especially when it comes to patient autonomy and the physician-patient relationship.
- 2. Gene Editing and CRISPR:** Advances in gene editing, particularly through technologies like CRISPR, have raised ethical concerns about the potential to edit human embryos or create “designer babies.” The ability to modify genetic traits leads to questions about the limits of such interventions, fairness in access to these technologies, and the implications for future generations. There is ongoing debate about the moral permissibility of germline editing and the potential for unintended consequences.
- 3. Global Health and Resource Allocation:** The COVID-19 pandemic highlighted ethical issues related to global health equity and the distribution of medical resources. Ethical discussions focus on how to fairly allocate limited resources during public health crises and how to prioritize vulnerable populations. Additionally, there is increased emphasis on addressing health disparities and ensuring that marginalized groups have access to adequate healthcare.
- 4. Patient Autonomy and Shared Decision-Making:** There has been a shift towards shared decision-making, where patients are increasingly

involved in decisions about their treatment. This approach requires healthcare providers to respect patients' preferences and values while ensuring that they are fully informed. This focus on autonomy extends to end-of-life care, reproductive health, and mental health, where patients' choices can sometimes conflict with conventional medical recommendations.

5. Ethics of Telemedicine: The rise of telemedicine, accelerated by the pandemic, introduces ethical questions about patient confidentiality, quality of care, and access. Telemedicine expands healthcare access, but there are concerns about maintaining privacy in virtual settings, ensuring equal access for all patients (particularly those in underserved areas), and preserving the quality of the physician-patient relationship in remote interactions.

6. Reproductive Rights and Privacy: Recent changes to laws governing reproductive rights, particularly in the U.S., have brought the ethics of reproductive healthcare into sharper focus. Ethical debates are centered on the balance between protecting patients' reproductive autonomy and privacy, and complying with changing legal frameworks. The ethical implications of new technologies, such as surrogacy, embryo donation, and prenatal screening, are also being actively discussed.

These developments in medical ethics reflect the need to continuously adapt ethical principles to contemporary challenges in healthcare, ensuring that patient rights and well-being remain at the forefront of medical practice

Healthcare, Law, and Ethics Summary

Several core medical ethics principles are deeply intertwined with legal frameworks, guiding healthcare providers in their professional conduct. Here are key medical ethics principles that relate closely to the law:

1. **Autonomy:** This principle emphasizes a patient's right to make informed decisions about their medical care. Legally, this relates to informed consent, where healthcare providers are required to ensure that patients understand the risks, benefits, and alternatives to a treatment before agreeing to it. Failing to obtain informed consent can result in legal claims of battery or negligence.

2. **Beneficence and Non-maleficence:** Beneficence refers to acting in the patient's best interest, while non-maleficence means avoiding harm. Legally, these principles are the foundation of malpractice law, which holds healthcare providers accountable for harm caused by substandard care. Medical professionals must provide a standard of care that aligns with legal expectations to avoid liability.

3. **Confidentiality:** Confidentiality in medical ethics is grounded in the right of patients to have their personal health information protected. This principle is legally enforced by laws such as the Health Insurance Portability and Accountability Act (HIPAA) in the U.S., which establishes strict guidelines for the handling and sharing of patient data.

4. **Justice:** This principle refers to fairness in medical treatment, including the equitable distribution of healthcare resources. Legally, justice is relevant in anti-discrimination laws and public health policies, ensuring that patients are treated without bias based on race, gender, socioeconomic status, or disability. For example, the Americans with Disabilities Act (ADA) protects patients from discrimination in healthcare settings.

5. **Fidelity:** Medical ethics also emphasizes the duty of healthcare providers to remain loyal and trustworthy to their patients, which translates into legal duties like duty of care and fiduciary responsibility. Breaches of

this trust, such as misrepresentation or failure to act in the patient's best interest, can lead to legal consequences, including lawsuits for breach of contract or malpractice.

6. End-of-life Decision-Making: Ethical principles concerning end-of-life care, such as respecting advance directives, align with legal documents like living wills and durable power of attorney for healthcare. These legal instruments ensure that a patient's wishes are followed when they are no longer able to communicate their decisions, and providers must adhere to these directives to avoid legal repercussions.

These principles and their legal counterparts work together to ensure ethical, fair, and lawful healthcare practices, while safeguarding patient rights and professional standards.



Biomedical Waste & Safety

Biomedical sharps waste is often regulated by county rules along with state and federal regulations. In California, the following rule applies for small quantity generators of medical waste:

For the two types of medical waste, biohazardous and sharps waste, the storage times do differ. A facility that generates less than 20 pounds of biohazardous waste per month may store it for 30 days. The waste may be stored for up to 90 days if kept at 32° F or below. Sharps waste can be stored for 30 days, once the container is full. To determine how frequently your facility requires pickup by a medical waste transporter, you should weigh the amount of biohazardous waste generated in one month. Do not include the amount of sharps waste generated in the weight.

California allows for medical sharps waste to be picked up by approved disposal companies. Keep a receipt and/or copy of the manifest to prove proper disposal of the waste. As with all areas, the waste must be stored in an approved container. California, along with many other states, allows mail-back systems for sharps containers, specially designed medical needle disposal containers. Mail-back sharps containers are prepaid sharps disposal containers that can be mailed back to the disposal company.

Florida statutes stipulate the following:

381.0098 Biomedical waste.—
(1) LEGISLATIVE INTENT.—Except as otherwise provided herein, the Department of Health shall regulate the packaging, transport, storage, and treatment of biomedical waste. The Department of Environmental Protection shall regulate onsite and offsite incineration and disposal of biomedical waste. Consistent with the foregoing, the Department of Health shall have the exclusive authority to establish treatment efficacy standards for biomedical waste and the Department of Environmental Protection shall have the exclusive authority to establish statewide standards relating to environmental impacts, if any, of treatment and disposal including, but not limited to, water discharges and air emissions. An interagency agreement between the Department of Environmental

Protection and the Department of Health shall be developed to ensure maximum efficiency in coordinating, administering, and regulating biomedical wastes.

(2) DEFINITIONS.—As used in this section, the term:

(a) “Biomedical waste” means any solid or liquid waste which may present a threat of infection to humans. The term includes, but is not limited to, nonliquid human tissue and body parts; laboratory and veterinary waste which contains human-disease-causing agents; discarded disposable sharps; human blood, blood products, and body fluids; and other materials which in the opinion of the department represent a significant risk of infection to persons outside the generating facility. The term does not include human remains that are disposed of by persons licensed under chapter 497.

(b) “Biomedical waste generator” means a facility or person that produces or generates biomedical waste. The term includes, but is not limited to, hospitals, skilled nursing or convalescent hospitals, intermediate care facilities, clinics, dialysis clinics, dental offices, health maintenance organizations, surgical clinics, medical buildings, physicians’ offices, laboratories, veterinary clinics, and funeral homes where embalming procedures are performed.

(c) “Department” means the Department of Health.

(d) “Sharps” mean those biomedical wastes which as a result of their physical characteristics are capable of puncturing, lacerating, or otherwise breaking the skin when handled.

(e) “Treatment” means any process, including steam treatment, chemical treatment, and microwave shredding, which changes the character or composition of biomedical waste so as to render it noninfectious. For the purposes of this section, treatment does not include the incineration of biomedical waste.

Many states stipulate differences between large and small generators of medical waste. Most acupuncturists tend to fall in the small generator category. Restrictions, permits and fees for large generators are more tightly regulated. This may be of concern in group practices wherein all acupuncturists are incorporated as a single entity. In this case, the practice may be classified as a large generator of medical sharps waste. The following Florida statute (381.0098) defines the differences between large and small generators for licensed acupuncturists in Florida:

(4) PERMITS AND FEES.—

(a) All persons who generate, store, or treat biomedical waste shall obtain a permit from the department prior to commencing operation, except that a biomedical waste generator generating less than 25 pounds of biomedical waste in each 30-day period shall be exempt from the registration and fee requirements of this subsection. A biomedical waste generator need not obtain a separate permit if such generator works less than 6 hours in a 7-day period at a location different than the location specified on the permit. The department may issue combined permits for generation, storage, and treatment as appropriate to streamline permitting procedures. Application for such permit shall be made on an application form provided by the department and within the timeframes and in the manner prescribed by department rule.

(b) Once the department determines that the person generating, storing, or treating biomedical waste is capable of constructing a facility or operating in compliance with this section and the rules adopted under this section, the department shall grant the permit.

Taking a look at requirements for sharps containers in Oregon, the same stipulations are nearly identical to other states:

Sharps and other medical waste

Medical sharps such as needles, IV tubing with needles, scalpel blades, lancets, glass tubes and syringes can harm people, pets and wildlife when discarded improperly. Placing hypodermic needles and other sharps in the trash, for example, exposes garbage haulers and other disposal workers to potential injury.

To reduce these risks, it's illegal in Oregon to dispose of medical sharps in the garbage. Instead, they must be put in approved sharps containers and disposed of safely. Source: oregonmetro.gov

Virginia has the same requirement by statute:

9VAC20-120-240. Sharps.

Sharps must be placed directly into puncture resistant containers as required by the general industry standards in 16VAC25-90-1910.1030(d)(4)(iii)(A).

The similarities persist in almost every jurisdiction. The following pertains to Colorado statutes:

Contaminated sharps (needles, syringes, lancets) must be placed in a puncture resistant container and be properly designated as untreated infectious waste or made noninfectious by an appropriate treatment method. Untreated containers of sharps cannot be compacted. [CSWR Section 13.8.4] Recognizable human anatomical remains cannot be disposed of at a solid waste landfill. These must be either incinerated or interred. [CSWR Section 13.4.4]

Concerns about a particular state's medical sharps waste restrictions can be referenced from the EPA's (epa.gov) website or on a state-by-state basis. The EPA lists each state and the statutes governing sharps waste. Canada, Australia and the UK have similar provisions and similarities.

We hope you enjoyed this presentation.



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