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# Safety In Acupuncture #3

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## **Pneumothorax**

Do not needle deeply over the lungs. Puncturing of the lungs causes pneumothorax, a collapsed or partially collapsed lung wherein there is air or gas in the pleural space. Accidental needling through the lung is iatrogenic pneumothorax, caused by a medical examination or procedure. This may be due to a biopsy or improper acupuncture needling technique.

Onset of pneumothorax is marked by sudden sharp chest pain, shortness of breath and an unproductive cough. Low blood pressure accompanied by more severe symptoms may also occur such as upper back pain, exhaustion and the patient may turn blue due to low oxygen levels. Mild pneumothorax may resolve without medical intervention. However, the only correct protocol if there is a pneumothorax is to make sure that the patient is brought to an emergency medical facility immediately. Pneumothorax is a medical emergency. Severe cases may require surgery. Positive diagnosis is confirmed by X-Ray, CT scan or evaluation of arterial blood gases.

There are many points in common acupuncture practice that must be needled carefully to avoid pneumothorax. These points include the following:

- LU1, LU2
- ST11, ST13, ST14, ST15, ST16, ST17, ST18
- UB11, UB12, UB13, UB14, UB15, UB41, UB42, UB43, UB44, UB45
- Kl23, Kl24, Kl25, Kl26, Kl27
- GB21

#### **LU1, LU2**

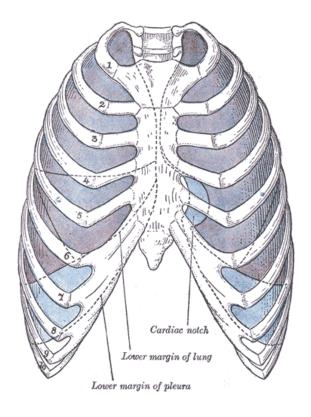
LU1 is located laterosuperior to the sternum at the lateral side of the 1<sup>st</sup> intercostal space, 6 cun lateral to the Conception Vessel. LU1 is 1 cun below LU2. LU1 is the front Mu pont of the Lung and is an intersection point of the Spleen channel. LU1 is indicated for the treatment of respiratory conditions including coughing and asthma. LU1 is needled 0.5 to 0.8 inches

obliquely and laterally. Avoid the lungs by avoiding a medial or deep insertion.



LU1, LU2, ST11-16, KI24-27 and other lung area points

LU2 is located in a depression below the acromial extremity of the clavicle, 6 cun lateral to the Ren Meridian. The point is located in the center of the depression formed by the deltopectoral triangle. LU2 benefits the lungs and is indicated for conditions including cough, asthma, chest pain and shoulder pain. This point is needled 0.5 to 0.8 inches laterally. Deep needling and medial needling is contraindicated and may cause pneumothorax.



# **Anterior Points: ST11, ST13, ST14, ST15, ST16, ST17, ST18**

Deep insertion at the following points may injure blood vessels and/or may cause pneumothorax. Use extreme caution and follow precise needling guidelines for licensed acupuncturists.

ST11 is located at the superior border of the sternal extremity of the clavicle between the sternal and clavicular heads of the sternocleidomastoideus muscle.

ST12 is located in the midpoint of the supraclavicular fossa, 4 cun lateral to the Ren Meridian.

ST13 is located at the lower border of the middle of the clavicle, 4 cun lateral to the Ren Meridian.

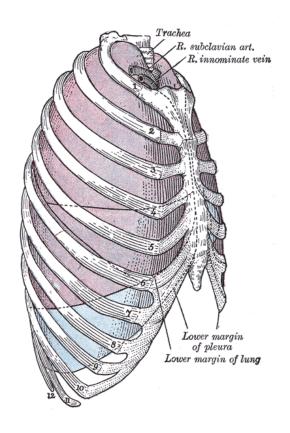
ST14 is located in the 1<sup>st</sup> intercostal space, 4 cun lateral to the Ren meridian.

ST15 is located in the 2<sup>nd</sup> the intercostal space, 4 cun lateral to the Ren meridian.

ST16 is located in the 3<sup>rd</sup> intercostal space, 4 cun lateral to the Ren meridian.

Not all acupuncture points are indicated for moxibustion and needling. ST17, located in the center of the nipple (mamilla) in the 4<sup>th</sup> intercostal space, is a forbidden point for both acupuncture and moxibustion. Piercing of this point for the application of jewelry is in common practice but may cause non-healing sores or cause permanent damage to the tissue.

ST18 is located below the nipple in the 5<sup>th</sup> intercostal space, 4 cun lateral to the Ren meridian.



## Back Points: UB11 (BL11), UB12, UB13, UB14, UB15

Deep insertion at the following points may injure blood vessels and/or may cause pneumothorax. Use extreme caution and follow precise needling guidelines for licensed acupuncturists.



Common points of the back over the lungs and other organs

UB11 is located 1.5 cun lateral to T-1, at the level of the lower border of the spinous process of the 1<sup>st</sup> thoracic vertebra.

UB12 is located 1.5 cun lateral to T-2, at the level of the lower border of the spinous process of the 2<sup>nd</sup> thoracic vertebra.

UB13 is located 1.5 cun lateral to T-3, at the level of the lower border of the spinous process of the 3<sup>rd</sup> thoracic vertebra.

UB14 is located 1.5 cun lateral to T-4, at the level of the lower border of the spinous process of the 4<sup>th</sup> thoracic vertebra.

UB15 is located 1.5 cun lateral to T-5, at the level of the lower border of the spinous process of the 5<sup>th</sup> thoracic vertebra.

## Back Points: UB41 (BL41), UB42, UB43, UB44, UB45

Deep insertion at the following points may cause pneumothorax. Use extreme caution and follow precise needling guidelines for licensed acupuncturists.

UB41 is located 3 cun lateral to the DU (GV) channel at the level of the lower border of the spinous process of the 2<sup>nd</sup> thoracic vertebra on the spinal border of the scapula.

UB42 is located 3 cun lateral to T-3 on the spinal border of the scapula.

UB43 is located 3 cun lateral to T-4 on the spinal border of the scapula.

UB44 is located 3 cun lateral to T-5 on the spinal border of the scapula.

UB45 is located 3 cun lateral to T-6 on the spinal border of the scapula.

### **Chest Points: KI23, KI24, KI25, KI26, KI27**

Like the UB channel points in this region, these Kidney channel points are located over the lungs. Deep needle insertion will cause pneumothorax is and contraindicated.

K23 is located 2 cun lateral to Ren 17 in the 4th intercostal space.

K24 is located 2 cun lateral to Ren 18 in the 3rd intercostal space.

K25 is located 2 cun lateral to Ren 19 in the 2<sup>nd</sup> intercostal space.

K26 is located 2 cun lateral to Ren 20 in the 1st intercostal space.

K27 is located 2 cun lateral to Ren 21 in the depression on the lower border of the clavicle.

#### **GB21**

GB21is located directly above the nipple midway between GV14 and the acromion at the highest point of the shoulder, at the crest of the trapezium muscle. GB21 is an intersection (meeting) point of the Triple Burner, Stomach and Yang Linking channels. GB21 is indicated for the treatment of apoplexy and hemiplegia due to stroke, mastitis, difficult labor, breast pain, scrofula, stiff neck and cervicalgia. This point is contraindicated for use during pregnancy.

Texts vary on needling depths and angles of insertion. The text <u>Chinese Acupuncture and Moxibustion</u> (Foreign Language Press, Beijing) notes that this point is needled perpendicularly 0.3 to 0.5 inches. Note the shallow insertion recommendation. The text does not mention the pinching-grabbing needle technique to the skin and muscle often taught in acupuncture schools as a precautionary measure. Needling techniques are beyond the scope of this course and are generally taught in live seminars or interactive environments. However, a discussion of needling methods from an academic perspective is important given that there is a high risk of pneumothorax if this acupuncture point is needled perpendicularly or deeply.

The text <u>Acupuncture</u>, <u>A Comprehensive Text</u> (Eastland Press) notes that the needling method for GB21 is "Straight insertion, 0.5-1 unit. Sensation: dissension and soreness extending to shoulder region. CAUTION: Care should be taken not to insert needle too deeply, to avoid puncturing the lung." GB21 is at the apex of the lungs. In some individuals, the apex is less than 1 cun under GB21 and a perpendicular insertion of 1 inch, cun or unit would cause pneumothorax. Therefore, the needle depth limit set in <u>Chinese Acupuncture and Moxibustion</u> is significantly safer and notably prohibits needling deeper than 0.5 inches.

A final comparison is taken from another respected acupuncture text, <u>A</u> <u>Manual of Acupuncture</u> (Deadman, Al-Khafaji, Baker; Journal of Chinese Medicine Publications). The needling method is described by the following: "Posterior oblique insertion, 0.5-1 cun. Caution: i. perpendicular insertion, especially in thin patients, carries a substantial risk of inducing a pneumothorax; ii. contraindicated in pregnancy." Here, the posterior oblique insertion angle is a more cautious approach than the perpendicular needling method suggested in <u>Chinese Acupuncture and Moxibustion</u> but the needling length is longer. Given the varying methods mentioned in each text, it is important to note that no one should attempt needling this point without having been trained in a professional acupuncture school or approved tutorial program. This point is extraordinarily common in clinical practice and requires caution.

## **General Needle Safety**

A needle is consider "stuck" when the practitioner cannot rotate, lift or thrust it. This may be due to a local muscles spasm, nervous tension, excessive twirling of a needle in one direction or if the patient has changed position. One method is to wait for the area to relax and then remove the needle. Another method is have the patient resume the original posture during which the needle was originally applied. The goal is to provide a relaxing environment for patients and one in which the patient will not change postures in an effort to prevent this effect. New patients often need to be reminded to remain relaxed in one position.

Manual application techniques are contraindicated for bent needles. Needles may be slowly removed by following the course of the bend or by returning the patient to the original posture during which the needle was originally applied.

If a needle is broken, maintain a calm environment for the patient to avoid movement. Remove the needle with forceps or by hand immediately. If the needle is flush with the level of the skin, depress the tissue surrounding the

needle site to expose the needle and remove. Needles embedded beneath the skin require surgery and is considered a medical emergency. The main goal is to never insert a needle up to the level of the handle. The shaft must always be visibly above the level of the skin surface.

#### **Cell Phones and Distractions**

Patients changing posture becomes challenging in the modern environment filled with distractions such as cell phones. Patients often reach for the cell phone to answer a call or use the device in some other fashion during the acupuncture treatment. Listening to a call is problematic in several ways that affect safety.

Patients may place the phone beside the ear thereby shifting points on the hands, arms and ears. At the Healthcare Medicine Institute (HealthCMi), we have received reports from acupuncturists of unusual behaviors associated with cell phone usage. It was reported that a patient with back Shu points got up off the table, walked to the chair and sat in it while answering the cell phone. The acupuncturist returned to check in on the patient to see that the patient was having a friendly conversation with a friend. Fortunately, the patient did not recline against the chair. This may have forced the needles towards the lungs and caused a pneumothorax. The acupuncturist removed the needles and no adverse affects were reported.

The takeaway here is to expect the unexpected. New patients may require instructions that may have been considered unnecessary several years ago; for example, do not get up from the acupuncture table while needles are retained. Updated instructions to patients may also be necessary due to the increasing pace of society. Patients may feel they want to rush once the needles are removed. After the needles are removed, a gentle reminder to move about slowly and resume a supine, prone or side resting position if dizziness, nausea or faintness is experienced may be necessary.

## **Avoiding Syncope & Adverse Reactions**

Lighter treatments using fewer needles are indicated for patients who have not eaten prior to treatment, have overeaten, are intoxicated or exhausted or are very weak. Patients who are hungry during an acupuncture treatment are more likely to experience adverse effects. In all of these cases, it may be indicated to reschedule the acupuncture appointment.

Fainting may occur if the patient's qi is weak or if the patient is stressed or hungry. Strong manipulation of the needles that exceeds the patient's constitutional ability to handle the stimulation may cause fainting. Common scenarios are the use of many needles, strong needle stimulation or the use of strong needle techniques when the patient is seated. Fainting is more likely in the seated position than in supine or prone positions because the patient requires qi to remain in an upright position or because viewing the needling techniques may be stressful for the patient.

Be sure to verbally check-in with patients when needling them in the seated position. Let them know to speak up if they feel faint, dizzy, sweaty or nauseas. Other signs and symptoms indicating removal of the needles and to have the patient rest in a supine position include: cold sweat, pallor, shortness of breath, vertigo, sudden drop in pulse intensity or blood pressure. Once any of these signs or symptoms occur, immediately remove all needles. Assist the patient to rest in a supine position, elevate the feet and offer the patient warm water. Acupressure to Sishencong may help to restore the patient to a sense of well-being and consciousness. If the patient faints and does not wake immediately it is indicated to press with the fingernail or needle one or more the following acupuncture points: GV26, GV25, PC9, PC6, ST36. Moxibustion may be applied to: GV20, CV4, CV6. If the patient does not revive quickly, emergency measures must be taken.

It is important to remind patients to get up from the treatment table slowly in order to prevent a hypotensive reaction and subsequent syncope. If a patient continues to feel disoriented after getting up, the acupuncturist may determine that the patient needs to rest on the table for a longer period of time or should remain at the office before attempting to drive a vehicle.

## **Cleansing the Area**

According to many clean field guidelines, 70% ethyl or isopropyl alcohol is the correct agent to be used to cleanse the skin with a cotton ball prior to acupuncture needling. The CCAOM (Council of Colleges of Acupuncture and Oriental Medicine) advises the following in its clean needle technique guidelines:

Once the hands of the practitioner are rewashed, the acupuncture points should be swabbed with an alcohol swab using 70% isopropyl alcohol. Use a new swab whenever the alcohol swab becomes dirty or contaminated or is too dry to leave a thin layer of alcohol solution on the skin. The insertion point can then be palpated with the washed finger.

A very high percentage of alcohol content is not preferred. This has a different drying rate that affects sanitisation and is therefore not recommended for clean field acupuncture preparation. According to the text Chinese Acupuncture and Moxibustion (Foreign Language Press, Beijing), the skin is cleansed with 75% alcohol or with 2.5% iodine that is then removed with 70% alcohol on a cotton ball. Specific guidelines for cleansing the skin vary by certifying bodies and organizations. Several US based clean needle technique course instructions include the use of 70% alcohol. Be sure to comply with the standards consistent with licensure in your state.

Rubbing alcohol is the general term used to denote a type of denatured alcohol used for disinfection. In the USA, this is typically 70 to 95% either isopropyl or ethyl alcohol. Heavy taxes and sales restrictions apply to alcohol that is fit for human consumption. Rubbing alcohol is made unfit for ingestion, denatured, by adding acetone, methyl isobutyl ketone and other additives to make the mixture poisonous for ingestion and to create a bitter flavor. Water is also added. As a result of the additives, rubbing alcohol can be sold without the heavy taxes that apply to alcoholic beverages. In addition, ingredients including acetone have a very drying effect and repeated use may cause cracking of the skin and dryness.

Denatonium is often added to make rubbing alcohol very bitter to prevent accidental and intentional ingestion. This chemical compound, often in the form of denatonium benzoate, is also added to nail biting prevention

formulas, animal repellants, windshield washing fluids, shampoos and antifreeze solutions. As a public policy matter, denatonium has been credited with preventing poisoning of children and animals and is required to be included in some poisonous household items by several state laws.

Methyl isobutyl ketone (hexone, methyl-isobutyl-cetone, MIBK) is a powerful solvent used as a denaturant in rubbing alcohol. The EPA (United States Environmental Protection Agency) notes that it has a low acute toxicity by inhalation and dermal exposure and moderate acute toxicity by ingestion. According to the EPA, chronic exposure to methyl isobutyl ketone "has been observed to cause nausea, headache, burning in the eyes, weakness, insomnia, intestinal pain, and slight enlargement of the liver in humans."

#### **Clean Field**

The following is an example taken from the State of California regulations and is representative of language applicable to many states regarding maintaining a clean field to work within.

#### 1399.451. Treatment Procedures.

- In treating a patient, an acupuncturist shall adhere to the following procedures:
- 1. (a) The acupuncturist's hands shall be brush-scrubbed with soap and warm water immediately before examining patients or handling acupuncture needles and other instruments, and between patients.
- 2. (b) All instruments shall be sterilized before and between uses in a manner which will destroy all microorganisms. All needle trays which contain sterile needles shall also be sterile. Each time instruments are sterilized, the acupuncturist shall use a tape or strip indicator which shows that sterilization is complete.
- 3. (c) Acupuncture points, where needles are to be inserted, shall be cleaned with an appropriate antiseptic before insertion of the needle.
- 4. (d) In the event an acupuncture needle inserted in a patient breaks subcutaneously, the treating acupuncturist shall immediately consult a physician. An acupuncturist shall not sever or penetrate the tissues in order to excise such a needle.
- 5. (e) Any complication, including but not limited to, hematoma, peritonitis or pneumothorax arising out of acupuncture treatment shall be referred immediately to a physician or dentist or podiatrist, if appropriate, if immediate medical treatment is required.
- 6. (f) Acupuncture shall not be performed using hypodermic needles.
- 7. (g )All instruments to be discarded shall be disposed of safely.

8. (h) Needles shall be disposed of by placing them in a sealed, unbreakable container marked "Hazardous Waste" and disposed of in accordance with state and local law.

1399.452. Treatments Outside the Office.

- 1. (a) Any acupuncturist who provides acupuncture treatment outside the office shall carry the required sterile needles and other instruments in a sterile airtight container.
- 2. (b) All standards of practice applicable to treatment outside the office shall be adhered to by the acupuncturist providing such treatment.

The following is another example of office hygiene and clean field regulations. The following is from the State of Florida Administrative Register & Florida Administrative Code, 64B1-8.

64B1-8.003 Office Hygiene.

An acupuncture office shall be maintained in a safe and sanitary manner.

64B1-8.004 Disposal of Biohazardous Waste.

Biohazardous waste must be managed pursuant to the provisions of Chapter 64E-16, Florida Administrative Code, effective June 3, 1997.

64B1-8.005 Infection Control Training.

Prior to commencement of clinical training, every approved course of study and tutorial program shall provide training in clean needle technique and universal precautions for preventing the transmission of bloodborn(e) pathogens and other infectious diseases, including, for example, HIV/AIDS, hepatitis, staphylococcus, and tuberculosis.

Most clean needle technique courses and regulations require that an acupuncturist's hands have been cleaned with soap and water and/or swabbed with a disinfectant, the skin of the needle site has been disinfected and that the sterility of the needle is maintained at the needle shaft upon insertion. In addition, the needle must be removed without the acupuncturist touching the shaft of the needle. The needle is disposed in a biohazard waste container and the practitioner cleans the hands again.

In some states and counties, storage of needles in biohazard containers is set to a maximum time limit before they must be picked up by or sent to a proper waste disposal company. In some counties and states, the area where used biohazard containers are stored must be labeled.

### **CPT Codes and Clean Needle Technique (CNT)**

97810 - Acupuncture, one or more needles, without electrical stimulation, initial 15 min.

97811 - Acupuncture, one or more needles, without electrical stimulation, each additional 15 minutes. With re-insertion.

97813 - Acupuncture, one or more needles, with electrical stimulation, initial 15 minutes.

97814 - Acupuncture, one or more needles, with electrical stimulation, each additional 15 minutes. With re-insertion.

CPT (Current Procedural Terminology) codes are the property of the American Medical Association (AMA). The CMS (Centers for Medicare and Medicaid Services) is the government agency that contracts the AMA to define and establish CPT codes.

The 97810 CPT billing code is for the application of manual acupuncture. Technically, it is for the application of one or more acupuncture needles during the initial phase of an acupuncture treatment wherein the acupuncturist has "personal one-on-one contact with the patient." The next code, 97811, is for each additional 15 minutes of acupuncture during that same treatment period. However, the code stipulates that there is a "reinsertion of needles" for it to be allowed. The same holds for the electroacupuncture billing codes 97813 for the first 15 minutes of electroacupuncture and 97814 for each additional 15 minutes.

The term "re-insertion" is an unfortunate choice since it seems to imply taking a needle out and putting it back in again. That would be a violation of clean needle technique and several state laws. A more legal interpretation and one that is consistent with clean needle technique is that reinsertion implies the addition of new sterile acupuncture needles. CPT codes are timed codes and therefore reinsertion is not required by some insurance carriers when there is additional direct time spent with the patient. This may include the application of manual acupuncture techniques and electroacupuncture.

The legal concern is to be sure that charges must be reasonable, defensible, consistent and are made public to patients. The clean needle technique concern is to always dispose of needles after one use. The exception is in states where reusable needles are allowed. In these cases, needles must be sterilized prior to reuse.

### **Reusable Needles**

Some states and countries allow reusable needles that have been sterilized with autoclave equipment. Many states, including California, do not allow reusable needles and only disposable needles are legal. Many acupuncturist malpractice insurance and health insurance network policies forbid the use of reusable needles.

## **Single Use Needle By State Examples**

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.

## **Medical Records**

Acupuncturists are required by law to maintain medical records for several years in most states and countries. Additional requirements for medical record retention may be made by malpractice insurance carriers. Health insurance companies may also require standards of medical records as prerequisite for reimbursement and participation in in-network panels. The State of California has this regulation:

1399.453. Record keeping.

An acupuncturist shall keep complete and accurate records on each patient who is given acupuncture treatment, including but not limited to, treatments given and progress made as a result of the acupuncture treatments.

The following is from the State of Florida rules and is representative of standard requirements in many areas:

64B1-10.001 Content and Retention of Medical Records.

- (1) Acupuncturists are required to maintain written medical records justifying the course of treatment of each patient. These records must include for each patient at least the following:
- (a) Patient's Medical History;
- (b) Acupuncture Diagnostic Impressions;
- (c) Points Used and/or Treatment Procedures Administered at Each Visit;
- (d) Acupuncturists' Recommendations;
- (e) Patient Progress Notes;
- (f) Laboratory test results when appropriate and medically necessary; and
- (g) Imaging films, reports or test results when appropriate and medically necessary.
- (2) All medical records must be maintained by the acupuncturist for a period of five (5) years from the date of the last entry to the record.

Medical records must be maintained for a period of 5 years in the above regulation. In some states, this requirement is significantly longer than 5 years. The general rule is to use SOAP notes in order to comply with state regulations. SOAP is an abbreviation for: subjective, objective, assessment, plan.

The S in SOAP is for the subjective portion of the chart notes. This includes information that the patient verbally relays to the acupuncturist. This may include the frequency, intensity and duration of a complaint. The patient history is included in this section. Technically, this information is not considered factual data.

The O in SOAP is for objective. This is considered factual data. Objectives are observations made directly by the acupuncturist or other medical professional. This includes a variety of information including test results. Blood pressure, weight, clinical observations, range of motion and other signs are noted here. The objectives may also include clinical observations concerning a patient's psychological state.

The A is for assessment. This is the diagnosis section. This may include a differential diagnosis according to Traditional Chinese Medicine (TCM) principles and a biomedical diagnosis. Some insurance carriers will not reimburse for acupuncturist services unless a biomedical diagnosis is made and a corresponding CPT code is assigned in the billing information. If a diagnosis cannot be made, a list of possible diagnoses may be included in this section. Evaluation of diagnostic tests and need for referral may be discussed in this section.

The P in SOAP is for plan. This is the determination of what type of treatment is to be rendered. This may include acupuncture points, herbal medicines, work restrictions and dietary recommendations. The plan may have both short term and long term goals for patient health.

SOAP notes may include abbreviations to assist in quick documentation of clinical findings. For example, *eap* is an abbreviation of electroacupuncture. Importantly, SOAP notes are legally confidential documents. Patient privacy laws apply. This includes the maintenance, storage and proper disposal of records.



## **Scope of Practice**

One of the most important clinical and legal guidelines is to engage only in activities within the defined scope of practice. This varies across countries and states. The following is a comparison of Florida and California to help get a general understanding of this parameter 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 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.

## **Biomedical Waste**

Many of the legal parameters discussed in this course differentiate rules and regulation between countries and states. Biomedical sharps waste, however, is often regulated by additional county rules.

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 statues 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.

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