ALC Occupational Licensing Review Subcommittee: Request for Information from the Arkansas Board of Acupuncture and Related Techniques.

#1 -- Which states do not require licensure and/or do not have safety regulations for acupuncturists?

Currently, there are three states which do not require licensure or have passed a practice act for the practice of acupuncture, Alabama, Oklahoma, and South Dakota. Four states have passed such acts since 2014, Kansas, North Dakota, Michigan, and Wyoming.

Alabama – Acupuncturists are not licensed in Alabama, there is no practice act for acupuncturists. ¹ The practice is governed by the States Medical Licensure Commission. ² The commission's regulation is as follows:

- (1) Acupuncture is deemed by the Medical Licensure Commission to be an experimental procedure of which the safety and medical effectiveness has not been established. The Commission therefore determines that while acupuncture practice by licensed physicians should not be absolutely prohibited, some safeguards are necessary to ensure that the public is not harmed or victimized by unprofessional practices, such as the unskilled or uninformed application of acupuncture treatment, or unfounded claims of effectiveness.
- (2) The Commission therefore determines that it shall be deemed unprofessional conduct, and grounds for action against the license of any physician pursuant to Code of Ala. 1975, § 34-24-360(a), for a physician to offer or administer acupuncture treatment except in compliance with the requirements set forth by the Federal Food and Drug Administration in Federal Register Vol. 88, No. 46, p 6419 (March 9, 1973). In administering this requirement, the Commission establishes the following criteria, which must be adhered to by physicians licensed by the Commission:
 - (a) All acupuncture devices in this state must be labeled properly according to applicable Federal Food and Drug requirements.³
 - **(b)** A physician must secure a patient's informed consent according to the guidelines established at 21 Code of Federal Regulations, § 130.37⁴, and no claims of therapeutic or diagnostic effectiveness may be made by a physician.
- (3) The Commission hereby announces its intention to require that physicians wishing to investigate and experiment with the use of acupuncture treatment must comply fully with the

¹ https://www.nccaom.org/state-licensure/#

² https://www.acufinder.com/Acupuncture+Laws/Alabama/3

³ <u>21 C.F.R. § 801.109</u> (Restricts possession of [medical] devices with potentially harmful effects to practitioners, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device –Restricts the sale of acupuncture needles to qualified acupuncturists) see 21 C.F.R. § 880.5580 (Acupuncture needles must conform with 21 CFR 801.109)

⁴ *While this citation is used in the Alabama Administrative code, I was unable to locate it.

above stated requirements of this Commission and with the requirement of the Federal Food and Drug Administration cited herein.⁵

Oklahoma – Acupuncturists are not licensed in Oklahoma, there is no practice act for acupuncturists.⁶ The practice of Acupuncture is considered within the scope of medical doctors and is controlled by the Oklahoma Board of Medical Licensure and Supervision.

[In Oklahoma] no chiropractic physician shall represent to the public that he/she is a specialist in the practice of Acupuncture and/or Meridian Therapy unless said chiropractic physician holds a registration issued by the Board stating that the chiropractic physician is proficient in Acupuncture and/or Meridian Therapy. The Board shall maintain a registry listing all chiropractic physicians who are authorized by the Board. This rule does not apply to chiropractic physicians licensed to practice chiropractic in Oklahoma who graduated from a chiropractic institution on or before January 1, 2000. The educational requirements include 100 hours of education in Acupuncture and must meet the following criteria:

- (1) Is conducted under the auspices of and taught by the postgraduate faculty of a fully accredited chiropractic college or institution, by a school of acupuncture recognized by the National Council of Acupuncture Schools and Colleges or by a school of acupuncture recognized by the Accreditation Commission for Acupuncture and Oriental Medicine.
- (2) Requires completion of a certification examination approved by the Board.; and
- (3) Meets other such criteria as the Board deems appropriate.8

The Board of Medical Licensure and Supervision and the Board of Chiropractic Examiners are able to regulate the practice of Acupuncture when it involves their own licensees, but it would seem that 21 CFR 801.109 [Footnote 3] would prevent a lay person from possessing the equipment necessary to practice acupuncture. (This distinction would apply to South Dakota and Alabama as well.)

Previous attempts to require certification from the national certification commission for acupuncture and oriental medicine (NCCAOM) or certification from local acupuncture schools have failed, the Oklahoma House of Representatives rejected the proposed laws because it would exclude many of the well-established practicing acupuncturists.⁹

South Dakota -- Acupuncturists are not licensed in South Dakota, there is no practice act for acupuncturists. The Attorney General of South Dakota issued an opinion that acupuncture is within the scope of the practice of chiropractors¹⁰¹¹ The South Dakota Board of Chiropractic Examiners requires

⁵ Ala. Admin. Code r. 545-X-4-.05 (Lexis Advance through the June 30, 2019 revisions)

⁶https://www.nccaom.org/state-licensure/

⁷ Okla. Admin. Code § 140:15-10-1

⁸ Okla. Admin. Code § 140:15-10-2

⁹ https://www.acupuncturetoday.com/mpacms/at/article.php?id=32835

¹⁰ <u>1975 S.D. AG LEXIS 136;</u>, <u>1975-1976 Op. Atty Gen. S.D. 249</u>

¹¹ <u>1975 S.D. AG LEXIS 137;</u>, <u>1975-1976 Op. Atty Gen. S.D. 251</u>

anyone wishing to be certified for acupuncture to pass the acupuncture test administered by the National Board of Chiropractic Examiners. ¹²

Medical Doctors (M.D.s) and Doctors of Osteopathy (D.O.s) have no minimum training requirements for acupuncture as it is considered within the scope of their practice.¹³

The South Dakota Acupuncture and Oriental Medicine Association¹⁴ has made efforts to pass legislation requiring acupuncture licensing in 2011, 2015, and now 2020.

#2 - Case data of instances where an individual was harmed by an unlicensed acupuncturist. E.g., injury, nerve damage, etc. (Any state)

The National Center for Acupuncture Safety and Integrity tracks injuries in the United States caused by people practicing acupuncture without an acupuncture license¹⁵:

- Since 2013, there have been 11 cases of pneumothorax (lung puncture) caused by unlicensed people practicing acupuncture. These injuries resulted in an average stay hospital stay of 4 days, and 7 of the 11 cases required surgical intervention.
- Since 2016 there have been 2 cases of injury to the cervical spinal cord, one requiring 3 days of hospitalization and the other an unknown number of days in an intensive care unit.
- In 2016 there was one case of injury to the thoracic spinal cord injury which resulted in hospitalization for 51 days.
- In 2017 there was one report of an infection in the thigh, requiring surgical drainage and IV antibiotics with hospitalization for 5 days.
- In 2012, there was a report of severe damage to a nerve in the thigh, resulting in severe pain, numbness, and paresthesia that requires medication.

A study analyzing the frequency and severity of adverse events reported for acupuncture over a 10-year period states that "it can be concluded that acupuncture has a very low rate of AEs (Adverse effects), when conducted among licensed, qualified practitioners in the West." "Any medical intervention has the potential to cause damage, particularly when administered by an untrained or unqualified practitioner, or in an unregulated setting." "In conclusion, although serious AEs associated with acupuncture are rare, acupuncture practice is not risk-free. Adequate regulation can even further minimize any risk. We recommend that not only adequate training in biomedical knowledge, such as anatomy and microbiology but also safe and clean practice guidelines are necessary requirements and should continue to be enforced." ¹⁶

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¹² https://doh.sd.gov/boards/chiropractic/assets/application.pdf

¹³ https://www.acufinder.com/Acupuncture+Laws/South+Dakota/42

¹⁴ https://www.sdaoma.org/

¹⁵ https://www.acupuncturesafety.org/ and

¹⁶https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3616356/ (Adverse Events of Acupuncture: A Systematic Review of Case Reports)

The National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) states that it takes "any reports of adverse effects from acupuncture, especially reports of deaths, very seriously and note that not a single death has been reported to result from acupuncture in the US. While promoters of most medical practices would consider a world-wide average of less than 2 deaths out of tens of millions of patients a year to be a remarkably low level of risk, we find these numbers unacceptable, and other Oriental approaches to medicine, are completely preventable when standards of competent practice are followed." ¹⁷

There are 61 NCCAOM Practitioners on Disciplinary Action (PEDR status).¹⁸ The NCCCAOM has a Professional Ethics and Disciplinary Committee (PEDC) whose function is to review disciplinary cases that involve its Diplomates, Candidates, and Applicants. Out of 117 cases, it reviewed between 2014-2017, 25 were related to malpractice/negligence, boundary violations, and unlicensed activity.¹⁹ These numbers do not include other disciplinary action taken by other professional associations or governing bodies.

While deaths caused by acupuncture are rare, they do occur: in 2016, an unlicensed Chinese acupuncturist was jailed for 10 years after the patient died where acupuncture was a contributing factor to the death. A report studying acupuncture related deaths found that about 90 deaths after acupuncture have been anecdotally documented in medical literature. Examples include: a 44-year-old Chinese woman with a history of diabetes and hypertension consulted an unlicensed acupuncturist in a rural setting. When an acupuncture needle penetrated her heart, the patient instantly complained of severe and alarming symptoms. Instead of taking urgent action, the acupuncturist inserted a further needle into her chest wall. The patient then died almost immediately. At autopsy, two punctures of the right ventricle were found. The second patient was a 26-year-old Chinese woman who consulted an acupuncturist for an unnamed reason. A needle penetrated her lung, and the patient died of tension pneumothorax. In conclusion, the report states that "deaths after acupuncture may be rare but they do occur. The best way to minimize the risk is to make sure that all acupuncturists are well-trained — not just in acupuncture technique but also in recognizing serious adverse events and initiating life-saving measures.

¹⁷ https://www.nccaom.org/blog/20<u>10/10/08/the-safety-of-acupuncture-and-oriental-medicine/</u>

¹⁸ https://pedr.nccaom.org/

¹⁹ https://www.nccaom.org/wp-content/uploads/pdf/2017%20NCCAOM%20Annual%20Report.pdf

²⁰ https://www.scmp.com/news/china/society/article/2054229/unlicensed-chinese-acupuncturist-jailed-10-years-after-patient

²¹ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2951167/ citing (*Ernst E.* Deaths after acupuncture: a systematic review. Int J Risk & Safety 2010;22:1–6)

²² https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2951167/#b7 citing (*Zhu WT, Li XS, Zhang YT, Li WN*. One case died from acupuncture-related cardiac rupture. J Forensic Med 2008;14:312)

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2951167/#b7 citing (Zhao D-Y, Zhang G-L. Clinical analysis on 38 cases of pneumothorax induced by acupuncture or acupoint injection. Chin Acupunc Moxibustion 2009;29:239–42)

²⁴ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2951167/

#3 -Data from pre/post enforcing a license regarding number of cases/complaints of harm

The Board and the Board's staff were unable to collect this documentation, and it may not be collectible.