Licensure, Scope of Practice, and Regulation of CAM Therapies

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Outline of Presentation

- Background (licensure; scope of practice)
- Regulatory & Policy Challenges
- Recommendations

Background - Licensure

- Key legal and regulatory issues :
  - licensure and credentialing
  - scope of practice
  - professional discipline
  - malpractice liability
  - right of access to treatments
  - third-party reimbursement
  - healthcare fraud.
    - Cohen MH. Complementary and alternative medicine: legal boundaries and regulatory perspectives. Baltimore: Johns Hopkins University Press. 1998.

Background - Licensure - Definitions

- Definitions
  - Licensure: the legal authority granted by a state legislature to practice a health care profession.
    - Scope of practice: the legally authorized boundaries of licensed practice (e.g., what a provider can and can't legally do).

Background - Licensure

- MD's have an "unlimited" scope of practice to diagnose and treat disease, while allied health providers (psychologists, nurses, physical therapists) and CAM providers have a scope of practice that is defined by a licensing statute.

Background - Evolution of Licensure

- Common law (1760s-1850s):
  - No licensing for any health care provider (anyone can practice).
    - Most practitioners are “ignorant, degraded, and contemptible” (President, New York Medical Society, 1818).
    - “Quacks abound among us like locusts in Egypt.”

Background - Evolution of Licensure

- States enact licensing laws, providing:
  - the practice of “medicine” requires state licensure;
  - unauthorized practice of “medicine” is a crime.

Background - Evolution of Licensure

- Medicine" is defined in terms of:
  - "diagnosing"
  - "treating"
  - "prescribing"
  - "operating"
    - … "for any human disease, pain, injury, deformity or physical condition …"
    - … "by attendance, advice, device, diagnostic test, or other means."

Background - Evolution of Licensure

- "Go to jail for chiropractic!"
  - early 20th-century slogan for the profession, as chiropractors are prosecuted for unlicensed medical practice.
  - "Medicine" is defined sufficiently broadly to include all healing arts.
  - Other convictions include massage therapists, naturopaths, herbalists, acupuncturists.

Background - Evolution of Licensure

- Licensing of CAM Providers in the U.S.:
  - 1900's: Chiropractic.
  - 1910's: Naturopathy.
  - 1960's: Massage therapy.
  - 1970's: Acupuncture/traditional oriental medicine.

Background - Legal Basis for Licensure

- The Tenth Amendment to the U.S. Constitution reserves to the states the power to regulate **health, safety, welfare, and morals**.

Background - Legal Basis for Licensure

- Licensure differs across states:
  - (1) by ***profession*** -- *who* gets licensed;
  - (2) by ***scope of practice*** -- *what* the providers are legally authorized to do;
  - (3) by ***training and education*** required for each profession; and
  - (4) by the ***kind*** **of licensure** afforded each provider.

Background - Kinds of Licensure

- Mandatory licensure
- Title licensure
- Registration
- Exemption
- Inclusion within Conventional Provider's Scope of Practice
- Minnesota Model
  - Combinations of the above.

Background - Kinds of Licensure

- Mandatory
  - Practicing the profession without a license is prohibited.
    - Example: “The unauthorized practice of psychology is prohibited.”
    - Anyone who practices “psychology” without a license may be prosecuted.

Background - Kinds of Licensure

- Title
  - Practicing the profession without a license is permitted, but one may not use the designated title without a license.
    - Example: “No person may use the title ‘massage therapist’ without a license.”

Background - Kinds of Licensure

- Registration
  - In order to practice the profession, a provider must register name, address, and training, with a designated state agency.

Background - Kinds of Licensure

- Exemption
  - A certain class of providers may be exempt from licensure or registration.
    - For example, religious healers typically are exempt from medical licensing statutes so long as they are practicing with the tenets of a recognized church.
    - Shiatsu practitioners and reflexologists may be exempt from massage therapy licensing requirements.

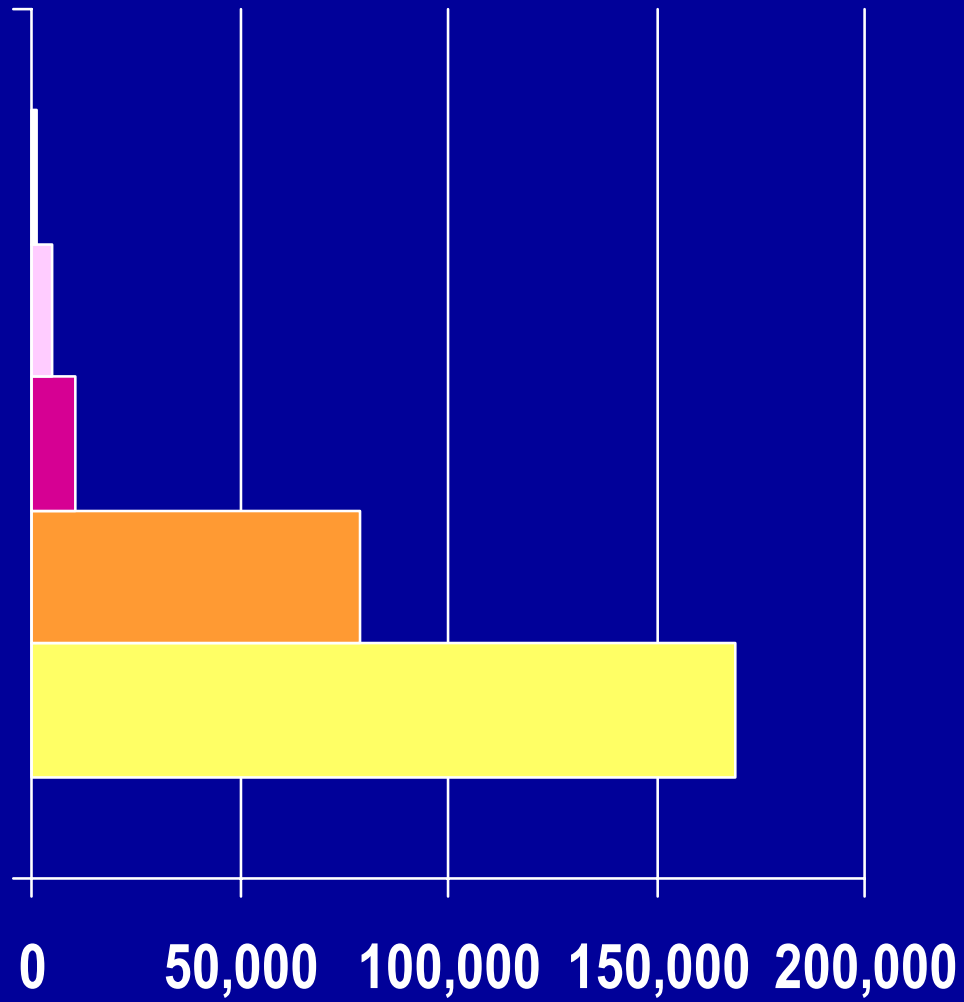
Background - Kinds of Licensure

- Inclusion within Conventional Provider's Scope of Practice
  - Psychologist offering
    - guided visualization and imagery
    - mindfulness meditation (MBSR)

Background - Kinds of Licensure

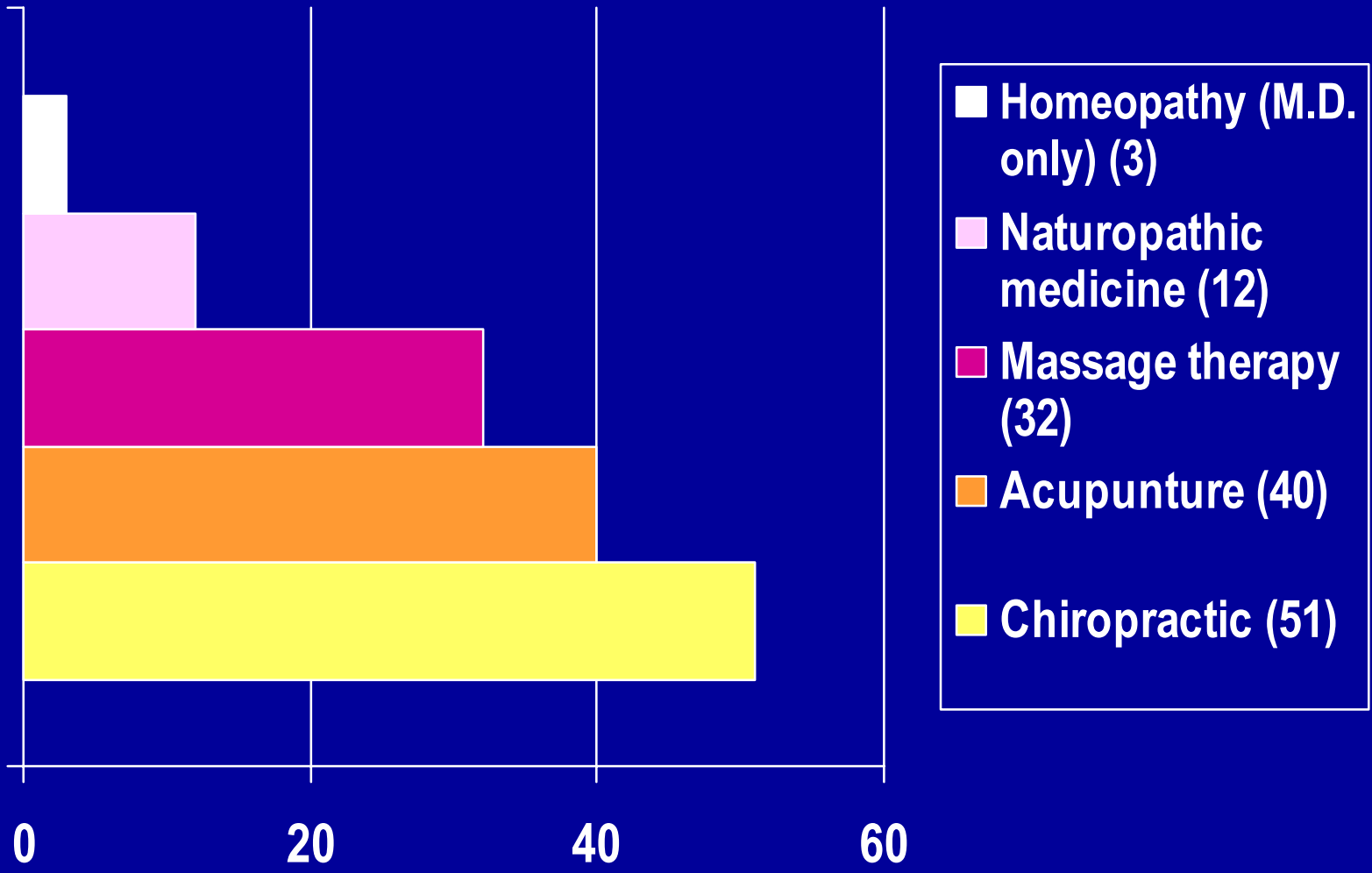
- "**Minnesota model**"
- Unlicensed providers of CAM services can practice, so long as they:
  - avoid *medical* diagnosis and treatment;
  - do not dissuade patient from medical care;
  - inform patients regarding their level of training and theory of practice; and
  - meet other disclosure requirements.
    - **California** and **Rhode Island** have enacted similar laws.

Licensure by Provider



- Naturopathic physicians (1,400)
- Acupuncturists (M.D.) (5,000)
- Acupunturists (non-M.D.) (10,500)
- Chiropractors (79,000)
- Massage therapists (169,000)

Licensure By State



Background - Scope of Practice

- *Licensed non-MDs* who **exceed their legally authorized scope of practice** *also* can be prosecuted for:
  - unlicensed medical practice, or,
  - unlicensed practice of other healthcare professions (e.g., massage; psychology).

Background - Scope of Practice

- Examples of boundary arenas:
  - Psychological/mental health counseling
  - Nutritional and dietary advice
  - Therapeutic use of touch

Background - Scope of Practice

- A chiropractor who recommends vitamins to a patient is prosecuted for unlicensed practice of “medicine,” even though the licensing statute provides that he may give “dietary advice.”
  - *Stockwell v. Washington State Chiropractic Disciplinary Board* (1981).

Background - Scope of Practice

- “Mere advice” differs from “prescribing” vitamins to treat disease, which constitutes unlicensed medical practice.
  - The court does not provide any basis or guidance for the distinction between dietary “advice’ and “prescribing” vitamins.
  - The court also acknowledges that the recommended supplements were commonly available in health food stores.

Background - Scope of Practice

- Patient visits chiropractor complaining of back pain.
- After examining patient's spine, chiropractor examines patient's elbow.
- Hearing officer: "it stretches logic as to how the x-ray of a right elbow" is within scope of practice.
  - *State v. Beno*, 373 N.W.2d 544 (Michigan 1985)

Background - Scope of Practice

- Appellate court: Chiropractor has acted appropriately since nerve interference may affect the elbow.
- Supreme court: Chiropractor has exceeded scope of practice and has practiced “medicine” unlawfully, since spinal misalignment cannot be diagnosed by examining the elbow.

Background - Summary

- Licensure:
  - is a political process;
  - is constantly in flux;
  - varies by state;
  - guarantees neither competence of providers or the safety or efficacy of therapies they offer;
  - is being undermined by the “Minnesota model.”

Background - Summary

- Scope of practice
  - also is a political process;
  - also varies by state;
  - also is constantly in flux;
  - is interpreted by courts in varying ways--even within a given state--and thereby results in an unpredictable patchwork of legal rules.

Regulatory & Policy Challenges

- ”How do you do national, multi-site research without some standards [e.g., greater standardization] in training, licensure, accreditation, and scope of practice?”

Regulatory & Policy Challenges

- Is greater standardization:
  - Desirable?
  - If desirable, feasible?

Regulatory & Policy Challenges

- **Desirable?**
- **Benefits** – increased standardization may:
  - facilitate physician collaboration and referral
  - facilitate more authoritative, consistent, and generalizeable research
  - increase quality of CAM providers
  - translate CAM therapies into standardized diagnostic and therapeutic codes for billing purposes.
    - Eisenberg, et al., Credentialing (2002).

Regulatory & Policy Challenges

- **Costs** - increased standardization may undermine:
  - the diversity of education, training and skill that characterize many CAM professions
  - individualization of services
  - amount and quality of time spent with patients
  - patient satisfaction
  - power of the therapeutic encounter.
    - Eisenberg, et al., Credentialing (2002).

Regulatory & Policy Challenges

- Costs - diversity
  - Even within a CAM profession, there is great diversity of therapeutic approaches and philosophies. Example - massage:
    - American Massage Therapy Association (AMTA)
    - Association of Bodywork and Massage Professionals (ABMP)
    - Association of Bodywork and Therapies of Asia (AOBTA)
    - Feldenkrais Guild
    - Nearly half of massage therapists do not belong to any professional organization.
      - Eisenberg, et al., Credentialing (2002).

Regulatory & Policy Challenges

- Desirable?
  - Even with better methodologies, many CAM practices are underpinned by culturally based understandings of health, and thus claim to occupy larger territory than defined by present evidence (e.g., understanding of *chi* vs. efficacy of acupuncture point X).
  - While clinicians rely on medical evidence, consumers may use personal experience.
  - Many assert a value to pluralism in healthcare and encouraging autonomous (but informed) choices ("access").

Regulatory & Policy Challenges

- Even if desirable, feasible?
  - Individual states have Constitutional authority to regulate healthcare providers.
  - Our model of federalism encourages states to be “laboratories for experimentation” and thus to offer diverse statutes, policies, and rules.
  - Legislative fiat (e.g., licensure and scope of practice) can trump medical evidence.
  - Judge-made law can interpret and thereby modify (or extend) this statutory fiat.

Regulatory & Policy Challenges

- Hospital policies are variable regarding:
  - CAM credentialing, limitations on practice authority, and provider mix in the integrative team;
  - CAM liability management strategies (including minimum malpractice liability insurance, informed consent practices and documentation, and provider hiring status); and
  - use or avoidance of dietary supplements.
    - Cohen MH, Hrbek A, Davis R, Schachter S, Eisenberg DM, *Emerging Credentialing Practices, Malpractice Liability Policies, Guidelines Governing Dietary Supplement Recommendations: A Descriptive Study of 19 U.S. Integrative Health Care Centers (in progress).*

Potential Recommendations

- 1. While licensure and scope of practice are matters of state law, the federal government could create a central agency to coordinate federal policy concerning CAM research and practice.
  - Final Report, White House Commission on Complementary and Alternative Medicine Policy (2002).

Recommendations

- Such an office (or the IOM Committee) could encourage and help CAM professional organizations to develop model legislation and guidelines (where feasible and appropriate) to:
  - increase standardization across states regarding:
    - minimum required education and clinical hours for licensure
    - curricular inclusion of biomedical components
    - certifying examination for licensure
    - scope of practice

Recommendations

- CAM professional organizations also could be encouraged to:
  - increase proportion of educational institutions within the profession that are professionally accredited
  - define or limit potentially misleading use of term “primary care provider”
  - enhance opportunities for licensees to participate in clinical residency in integrative care centers
  - create educational tools for medical clinicians and researchers explaining the diversity of therapeutic models and approaches.

Recommendations

- 2. Encourage relevant professional organizations and agencies to view integrative clinical care centers as educational hubs in which biomedical and CAM clinicians and researchers can explore shared and divergent theories and practices, and receive the cross-disciplinary training that may be necessary for integrative care.

Recommendations

- 3. Encourage institutional review boards to include CAM providers and other expertise relevant to evaluation of protocols and risks to human subjects in research studies involving study of CAM therapies.

Recommendations

- 4. Encourage researchers to develop **protocols** that limit the modalities specified providers are allowed to use ***for purposes of implementing clinical trials***, and thereby achieve the standardization necessary for multi-site data collection and analysis.

Conclusion

- In crafting policy, balance the:
  - desire for standardization, with appreciation for treating individuals
  - concern for evidence-based decisions, with respect for freedom of informed choice
  - desire to prevent fraud, with the wish to honor autonomy
  - interest in regulating healing, with trust for the therapeutic encounter
  - drive to understand mechanism, with allowance for mystery in healing.