

Legal Guidelines for Aromatherapy Practice and Aromatic Product Manufacturing

Important Disclaimer: This information is provided solely for educational purposes and should not be interpreted as legal counsel. While every effort has been made to ensure accuracy, we cannot guarantee that all information is completely current or correct. Laws, regulations, and their interpretations change frequently and vary by jurisdiction. Individuals should consult with qualified legal professionals regarding their specific circumstances and requirements.

Note: These guidelines apply specifically to the United States. International regulations governing aromatherapy practice and aromatic products differ significantly worldwide.

Professional Practice and Education

Are aromatherapists required to be licensed in the United States?

Healthcare and wellness practice licensing occurs at the state level. Currently, no state requires specific licensing or certification for aromatherapists that would prevent individuals from using, recommending, or dispensing essential oils and aromatic products. However, several states including California have incorporated natural remedies, sometimes specifically including aromatic therapies, within the scope of practice for licensed Naturopathic Doctors (ND) and Licensed Acupuncturists (LAc).

No state-level aromatherapy licensing exists beyond those connected to acupuncture licenses. Importantly, existing licenses do not prohibit other healthcare professionals or practitioners from using, dispensing, or recommending aromatic products, though the specific legal protections afforded to license holders regarding aromatherapy practice may not always be clearly defined.

Non-licensed credentials include various aromatherapy certifications offered by professional organizations and educational institutions.

Many aromatherapy organizations support maintaining freedom of practice rather than mandatory licensing requirements.

What legal protections exist for aromatherapy practitioners?

Without specific licensing, the First Amendment protects your right to share information with clients about health and wellness topics. However, this protection is limited by the requirement to avoid practicing medicine without proper authorization.

Medical practice regulation occurs at the state level, and aromatherapists should become familiar with their state's specific statutory language. Generally, only licensed physicians (and sometimes other designated professionals like nurse practitioners) may legally diagnose, prescribe treatments for, or claim to cure diseases.

Aromatherapists who are not medical doctors should be transparent with all clients and the public about their scope of practice. Professional organizations strongly recommend using comprehensive Informed Consent and Disclosure forms that clearly explain these limitations.

To avoid unauthorized medical practice, aromatherapists should understand these restrictions as they apply to all forms of communication: verbal discussions with clients and the public, written recommendations, educational materials, brochures, and website content.

Additionally, if you provide aromatic products to clients while using language that could be interpreted as diagnosing, preventing, treating, or curing diseases, you may violate FDA and FTC regulations regarding product claims, as the aromatic remedy could then be classified as an unapproved drug.

Various state-based Health Freedom initiatives are working to reduce some legal restrictions on aromatherapists and other holistic practitioners, with varying degrees of limited success. For current information, visit organizations focused on health freedom advocacy.

State Health Freedom and Safe Harbor Laws

Eleven states currently have Safe Harbor Practitioner Exemption Laws that protect access to complementary and alternative healthcare practitioners, including aromatherapists, who do not hold state licenses. These laws provide legal protection for unlicensed practitioners as long as they comply with specific provisions and requirements.

States with Current Safe Harbor Laws:

- Idaho (1976) - First state with safe harbor medical law, provides statutory exemption to Medical Practice Act
- Oklahoma (1994) - Parameters for Jurisdiction of Physician Licensing Act
- Minnesota (1999) - Freedom of Access to Complementary and Alternative Health Care Practitioners (specifically mentions aromatherapy)
- California (2002) - Senate Bill 577, which protects access to alternative and complementary medicine
- Arizona (2008) - Limited exemption for homeopaths only
- New Mexico (2009) - Unlicensed Health Care Practice Act (specifically includes aromatherapy under "complementary and alternative health care service")
- Colorado (2013) - Natural Health Consumer Protection Act
- Nevada (2015) - Healing Arts Bill for Wellness Services
- Maine (2019) - Act To Establish the Right To Practice Complementary and Alternative Health Care Act

Key Safe Harbor Law Provisions:

Permitted Practices: Safe harbor laws allow non-licensed practitioners to legally operate as long as they comply with specific provisions. For example, New Mexico's law specifically protects aromatherapists from violating medical licensing laws when providing complementary and alternative health care services.

Required Disclosures: Most safe harbor laws require practitioners to provide written disclosure documents (informed consent) to clients that include:

- Practitioner's name and contact information
- Types of therapeutic practices offered
- Practitioner's qualifications
- Statement that they are not licensed healthcare practitioners
- Nature and expected results of services to be provided

Prohibited Activities: Safe harbor laws typically prohibit unlicensed practitioners from:

- Performing surgery or puncturing the skin
- Prescribing or dispensing prescription drugs or controlled substances
- Making medical diagnoses
- Claiming to be licensed healthcare professionals

Additional State Initiatives:

Fifteen additional states have introduced similar health freedom legislation within the past ten years, with more states preparing to do so in the future. States currently working on safe harbor legislation include Massachusetts and Connecticut.

Benefits for Aromatherapy Practitioners:

Health Freedom and safe harbor laws provide greater opportunity for aromatherapists to practice ethically without fear of violating "practicing medicine without a license" definitions. These laws allow practitioners to legally provide aromatherapy services while following specific guidelines and disclosure requirements.

Important Note: Even in states with safe harbor laws, aromatherapists must still comply with all applicable product regulations (such as MoCRA for cosmetic products) and avoid making disease-related claims about their services or products.

Remember that ethical practices extend beyond legal requirements. Professional aromatherapy organizations provide ethics guidelines as valuable resources.

Are educational workshops and aromatherapy walks subject to the same restrictions as client consultations?

No. When providing information in purely educational settings—with no connection to specific products, product lines, or brands, and without giving individual health advice—you have broader freedom to discuss the therapeutic properties and traditional uses of essential oils and aromatic plants. This includes leading plant walks, teaching classes, or writing articles and books.

However, these boundaries can blur quickly. A workshop discussion might evolve into health recommendations, or an in-class assessment could potentially be considered clinical rather than educational. The First Amendment has limitations, and practitioners remain both ethically accountable and potentially legally liable for their communications.

Product Development and Manufacturing Regulations

What is MoCRA and how does it affect aromatherapy products?

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) is the primary legislation governing most aromatherapy products in the United States. MoCRA represents the first major update to cosmetic regulations since 1938 and significantly impacts how aromatherapy products are regulated, manufactured, and marketed.

Most aromatherapy products fall under cosmetic regulations because they are:

- Applied to the human body for cleansing, beautifying, promoting attractiveness, or altering appearance
- Intended for topical use (massage oils, body sprays, skincare blends, bath products)
- Used for aromatherapeutic benefits through skin application

Current MoCRA Requirements for Aromatherapy Businesses:

- **Facility Registration:** Most cosmetic manufacturers must register their facilities with the FDA. The deadline for existing facilities was July 1, 2024. New facilities must register within 60 days of beginning operations.
- **Product Listing:** Manufacturers must list their cosmetic products with the FDA, including ingredient information. Initial deadline was July 1, 2024, with annual updates required.
- **Good Manufacturing Practices (GMPs):** While MoCRA authorizes FDA to establish GMP requirements, the proposed regulations are not expected until October 2025, with final rules likely in 2026.
- **Adverse Event Reporting:** Manufacturers must report serious adverse events to the FDA within 15 business days. This requirement has been in effect since December 29, 2023.
- **Safety Substantiation:** Manufacturers must have adequate evidence that their cosmetic products are safe when used as intended. Records must be maintained to support safety claims.
- **Labeling Requirements:** Products must meet specific labeling requirements including ingredient disclosure and contact information for adverse event reporting.

- **Records Maintenance:** Manufacturers must maintain certain records related to safety and adverse events.

What is the MoCRA Small Business Exemption for Aromatherapy Products?

Thanks to advocacy efforts by organizations like the Handmade and Small Cosmetic Businesses Coalition (HSCG) and others, qualifying small aromatherapy businesses receive important exemptions under MoCRA.

Small Business Exemptions:

If your aromatherapy business qualifies as "small," you are exempt from:

- Compliance with Good Manufacturing Practices (GMPs)
- Facility Registration with the FDA
- Product Listing with the FDA
- Keeping records of adverse events for 6 years

Qualification Requirements:

To qualify as a small business under MoCRA, you must meet both criteria:

1. **Annual Revenue Limit:** Your cosmetic product sales revenue must be less than \$1 million per year (2023 amount, adjusted annually for inflation). This is calculated as the average of the previous 3 years' income.

Revenue Calculation Examples:

- Business A: 2022: \$800,000, 2021: \$750,000, 2020: \$650,000 Average: \$733,333
→ **Qualifies as small business**
- Business B: 2022: \$1,200,000, 2021: \$900,000, 2020: \$800,000 Average: \$966,667
→ **Qualifies as small business**
- Business C: 2022: \$1,100,000, 2021: \$1,200,000, 2020: \$900,000 Average: \$1,066,667
→ **Does NOT qualify as small business**

2. **Product Restrictions:** You cannot manufacture certain restricted cosmetic products including:
 - Products that regularly contact eye mucous membranes (eye shadow, mascara, eye makeup remover, liquid eyeliner for waterline, eyelash adhesive)
 - Injectable cosmetic products
 - Products intended for internal use
 - Products intended to alter appearance for more than 24 hours that consumers don't normally remove (permanent makeup, brow/eyelash dye, acrylic nails, gel nail polish)

Note: Most aromatherapy products (massage oils, body butters, skincare blends, room sprays used topically) would not fall into these restricted categories.

What Small Businesses Must Still Comply With:

Even qualifying small businesses must comply with these MoCRA sections:

- **Section 605:** Adverse Events reporting (serious adverse events must still be reported)
- **Section 608:** Safety Substantiation (you must have evidence your products are safe)
- **Section 609:** Labeling requirements (proper ingredient listing and warnings)
- **Section 610:** Records maintenance (certain safety-related records)
- **Section 611:** Mandatory Recall Authority (FDA can order recalls if necessary)

What about aromatherapy products intended for ingestion?

Aromatherapy products intended for internal use (such as essential oil supplements or products meant to be consumed) would fall under the **Dietary Supplement Health and Education Act (DSHEA)** rather than MoCRA cosmetic regulations. These products face more stringent requirements including:

- Good Manufacturing Practices (GMPs) with no small business exemption
- Facility registration requirements
- Specific labeling requirements including Supplement Facts panels
- Structure/function claim limitations
- Pre-market notification requirements for health claims

Important: The intended use determines the regulatory category. The same essential oil could be regulated as a cosmetic (when sold for topical aromatherapy use) or as a dietary supplement (when sold for internal consumption).

What labeling requirements apply to aromatherapy cosmetic products?

Required Label Elements Under MoCRA:

- **Product Identity:** Clear identification of what the product is
- **Net Quantity:** Weight or volume of contents
- **Ingredient List:** All ingredients listed in descending order of predominance by their INCI (International Nomenclature of Cosmetic Ingredients) names or common names
- **Manufacturer Information:** Name and address of manufacturer, distributor, or responsible party
- **Warnings:** Any necessary safety warnings or directions for safe use

Additional Considerations:

- Essential oils must be listed by their proper names (e.g., "Lavandula angustifolia (Lavender Oil)")
- Fragrance allergens above certain thresholds must be specifically declared
- Products making cosmetic claims should avoid language suggesting they diagnose, treat, cure, or prevent diseases

- "Natural" and "organic" claims must be substantiated and may be subject to additional regulations

Do I need to register my aromatherapy business facilities?

- **For Small Businesses:** If you qualify for the MoCRA small business exemption, facility registration is not required.
- **For Larger Businesses:** If your business does not qualify for the small business exemption, you must register your manufacturing facility with the FDA. The deadline for existing facilities was July 1, 2024. New facilities must register within 60 days of beginning cosmetic manufacturing or processing.

Recommendation: If you're uncertain about your qualification status, consider registering anyway to ensure compliance, as the registration process helps establish your commitment to regulatory compliance.

What about aromatherapy products I make at home for clients?

Currently, the FDA appears to use discretionary enforcement for individual practitioners who create custom aromatic blends for clients as part of individualized consultations, similar to their approach with herbalists. However, this is not a formal exemption, and the FDA could change this approach at any time.

Individual aromatherapists should:

- Familiarize themselves with MoCRA requirements
- Implement safety best practices including proper ingredient identification and documentation
- Use clear informed consent forms explaining the scope of their practice
- Avoid making disease-related claims
- Consider whether their practice scale might require full compliance

What are the current MoCRA implementation timelines?

Already in Effect (as of December 29, 2023):

- Serious adverse event reporting (15-day reporting requirement)
- Safety substantiation requirements
- Professional use labeling requirements
- Contact information requirements on labels
- FDA recall authority

Completed Implementation:

- Facility registration and product listing deadline: July 1, 2024
- Facility registrations must be renewed every two years

Upcoming Implementation (Still Being Finalized):

- Good Manufacturing Practices (GMP) regulations: Notice of Proposed Rulemaking expected by October 2025
- Fragrance allergen labeling requirements: Notice of Proposed Rulemaking expected by January 2025
- Asbestos testing methods for talc-containing products: Timeline being revised
- PFAS assessment report: Required by December 2025

Important Note: The FDA has revised and delayed several target dates from the original MoCRA timelines, providing the industry additional time to prepare for compliance. Businesses should monitor FDA announcements for updated implementation schedules.

What additional requirements should aromatherapy businesses know about?

- **State Regulations:** States may have additional requirements for cosmetic manufacturers, including business licensing, sales tax registration, and specific labeling requirements.
- **Alcohol Regulations:** If you use ethyl alcohol in your products, you may need to pay federal excise taxes unless you qualify for specific exemptions. State alcohol regulations vary significantly.
- **Organic Claims:** Products labeled as "organic" must comply with USDA organic standards or other certified organic programs.
- **International Shipping:** Products shipped internationally must comply with the destination country's cosmetic regulations, which may differ significantly from U.S. requirements.
- **Professional Liability:** Consider professional liability insurance for your aromatherapy practice and product manufacturing activities.

Remember: This information provides general guidance only. MoCRA implementation is ongoing with various phases that have rolled out through 2024 and continue into 2025-2026. The FDA has revised several target dates from original MoCRA timelines, providing the industry additional time to prepare for compliance. Always consult with qualified legal professionals and stay current with regulatory changes affecting your specific practice and business model. For current updates, businesses should follow @FDACosmetics on social media and subscribe to FDA cosmetics email updates.