COMPREHENSIVE REPORT:

Med Spa/Aesthetic Clinic Regulations

Controlled Substance Compounding and Prescriber Dispensing by PAs/APRNs

Jacob Creel, PharmD, CHC

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DISCLAIMER

This report is provided for informational purposes only and does not constitute legal advice. The analysis presented herein is based on publicly available regulatory documents and statutes as of March 2026. Readers should consult with qualified legal counsel licensed in the relevant jurisdiction(s) before making any decisions or taking any actions based on this information. Laws and regulations change frequently,

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A 3-JURISDICTION ANALYSIS

EXECUTIVE SUMMARY

Overview of the Regulatory Landscape

Based on the analysis of Alabama, Texas, and Floridaâ€”three states representing diverse regulatory approaches to med spa and aesthetic clinic operationsâ€”a highly restrictive regulatory landscape emerges for PA/APRN dispensing and compounding activities. All three jurisdictions impose significant limitations that exceed federal baseline requirements, particularly targeting controlled substance dispensing in outpatient aesthetic settings. The regulatory framework reflects heightened scrutiny of prescriber dispensing models, with state pharmacy boards, medical boards, and nursing boards creating overlappingâ€”and sometimes conflictingâ€”requirements that create substantial compliance challenges for aesthetic clinics seeking to dispense or compound medications.

The analysis reveals a clear regulatory trend: states are actively restricting or prohibiting traditional prescriber dispensing models in aesthetic medicine contexts, particularly for controlled substances. Alabama and Texas both prohibit PA/APRN prescribing of Schedule II controlled substances in outpatient settings, while Florida has implemented near-total prohibitions on dispensing practitioner distribution of Schedule II and III substances outside narrow surgical exceptions. Additionally, all three states distinguish between simple reconstitution (generally permitted under prescriber licenses) and bulk compounding (requiring pharmacy licensure or strict USP compliance with facility oversight), creating a critical compliance distinction that many aesthetic clinics may not recognize.

Regulatory Coverage Statistics

Note: This analysis covers 3 jurisdictions (Alabama, Texas, Florida) as provided in the comparison table. A complete 52-jurisdiction analysis would require additional state-by-state research.

From the 3 states analyzed:

- **States with explicit Schedule II regulations:** 3 out of 3 (100%)
- **States with explicit Schedule III-V regulations:** 3 out of 3 (100%)
- **States with explicit non-controlled substance regulations:** 3 out of 3 (100%)
- **States explicitly prohibiting PA/APRN Schedule II prescribing in outpatient/aesthetic settings:** 2 out of 3 (Alabama, Texas)
- **States prohibiting dispensing practitioner distribution of Schedule II/III:** 1 out of 3 (Florida, with narrow surgical exceptions)
- **States restricting physician office dispensing:** 1 out of 3 (Texas, except rural areas â‰¤5,000 population)
- **States requiring pharmacy licensure or 503B registration for sterile compounding:** 2 out of 3 (Texas, Florida)

Common Regulatory Approaches

Prohibition of PA/APRN Schedule II Prescribing in Outpatient Settings: Two of three states (Alabama, Texas) explicitly prohibit PAs and APRNs from prescribing Schedule II controlled substances in outpatient or med spa environments, with narrow exceptions only for hospital or hospice settings. This represents a significant restriction beyond federal DEA authority.

Distinction Between Simple Reconstitution and Bulk Compounding: All three states recognize simple reconstitution (adding diluent to manufacturer-supplied powder in single-dose vials) as a permitted activity under prescriber licenses, but classify bulk compounding as a pharmacy practice requiring either pharmacy licensure or strict compliance with USP standards under pharmacy board oversight.

Sterile Compounding Restrictions for "Office Use": Texas and Florida have implemented requirements that effectively prohibit or severely restrict pharmacies from providing sterile compounded medications for practitioner "office use" unless the pharmacy holds 503B outsourcing facility registration, reflecting post-2012 NECC fungal meningitis outbreak regulatory responses.

Weight Control Controlled Substance Prohibitions: Alabama explicitly prohibits PAs and APRNs from prescribing any controlled substances for weight control purposes, directly impacting aesthetic clinic use of Schedule III-IV appetite suppressants (Ala. Admin. Code r. 540-X-12).

Tri-Board Jurisdictional Overlap: All three states demonstrate overlapping and sometimes conflicting authority among pharmacy boards, medical boards, and nursing boards regarding dispensing, compounding, and facility licensure requirements, creating compliance uncertainty.

Notable Outliers and Unique Requirements

Alabama - Alternating Prescription Requirement for PA/APRN Schedule II: Alabama requires that when PAs or APRNs prescribe Schedule II controlled substances (in permitted settings), prescriptions must alternate every 30 days with the supervising physician, creating a unique collaborative prescribing model not identified in Texas or Florida (Ala. Admin. Code r. 540-X-4-.06).

Texas - Population-Based Office Dispensing Prohibition: Texas uniquely prohibits physician office dispensing except in rural areas with populations of 5,000 or fewer, creating a geographic restriction that effectively eliminates dispensing practitioner models in urban and suburban areas where most aesthetic clinics operate (Tex. Occ. Code Â§ 562.154).

Florida - Surgical Exception Time Limits: Florida permits dispensing practitioners to dispense Schedule II controlled substances only for 3-7 days post-operatively and Schedule III for 14 days post-operatively, creating specific day-supply limitations tied to surgical procedures rather than general prescribing authority (Fla. Stat. Â§ 465.0276(1)(b)).

Alabama - Complete PA/APRN Compounding Prohibition: Alabama explicitly states that PAs and APRNs "CANNOT compound medications," creating an absolute prohibition that extends beyond controlled substances to all compounding activities, requiring pharmacy involvement for any compounding beyond simple reconstitution (Ala. Code Â§ 34-23-50).

Florida - 2018 Office-Use Sterile Compounding Rule Change: Florida implemented a significant 2018 regulatory change prohibiting pharmacies from compounding sterile drugs for practitioner "office use" unless the pharmacy holds 503B federal registration, representing a major shift that eliminated traditional office-use compounding models (Fla. Admin. Code R. 64B16-27.700).

Regional Patterns

Southern State Restrictive Approach: All three analyzed states (Alabama, Texas, Florida) represent southern jurisdictions that have adopted notably restrictive approaches to prescriber dispensing and mid-level practitioner controlled substance authority in outpatient aesthetic settings. This may reflect regional responses to opioid epidemic concerns and aesthetic medicine industry growth in these states.

Post-2012 Compounding Crisis Response: Texas and Florida both demonstrate regulatory frameworks heavily influenced by the 2012 NECC fungal meningitis outbreak, with requirements that effectively mandate 503B registration for sterile compounding intended for practitioner office use, suggesting states with significant compounding-related adverse events may adopt stricter oversight.

Limited Regional Analysis: With only three states analyzed, definitive regional patterns cannot be conclusively established. A complete 52-jurisdiction analysis would be necessary to identify broader geographic trends (e.g., Northeast vs. West Coast approaches, state medical board vs. pharmacy board primary authority patterns).

Key Findings for Compliance Teams

1. PA/APRN Schedule II Authority is State-Specific and Often Prohibited in Aesthetic Settings: Despite federal DEA authority, 2 of 3 analyzed states prohibit PA/APRN Schedule II prescribing in outpatient/med spa contexts. Compliance teams must verify state-specific mid-level practitioner authority rather than relying on federal DEA registration alone. Alabama and Texas explicitly exclude outpatient aesthetic settings from PA/APRN Schedule II authority.

2. Simple Reconstitution â‰ Compounding for Regulatory Purposes: All three states distinguish simple reconstitution (adding diluent to manufacturer-supplied single-dose powder) from bulk compounding. Aesthetic clinics performing only simple reconstitution may operate under prescriber licenses, but any bulk preparation, combining multiple ingredients, or preparing multiple doses requires pharmacy licensure or pharmacy oversight with USP compliance.

3. Dispensing Practitioner Models Face Severe Restrictions or Prohibitions: Texas prohibits physician office dispensing except in rural areas (â‰¤5,000 population), and Florida prohibits dispensing practitioner distribution of Schedule II/III except for 3-14 day post-surgical supplies. Aesthetic clinics relying on dispensing practitioner models must verify state-specific authorization, as traditional office dispensing may be prohibited regardless of DEA registration.

4. Sterile Compounding for "Office Use" Requires 503B Registration in Multiple States: Texas and Florida effectively require pharmacy 503B outsourcing facility registration for sterile compounding intended for practitioner office use. Aesthetic clinics cannot assume traditional 503A pharmacies can provide sterile compounded medications (including semaglutide, tirzepatide, or testosterone) for in-office administration without verifying 503B status.

5. Tri-Board Conflicts Create Compliance Gaps: Pharmacy boards, medical boards, and nursing boards issue overlapping and sometimes conflicting guidance on dispensing, compounding, facility licensure, and supervision requirements. Compliance teams must review regulations from all three boards and identify conflicts, as relying on a single board's guidance may result in violations of another board's requirements. Alabama's 2024 Board of Medical Examiners Declaratory Ruling demonstrates ongoing regulatory clarification needs.

Emerging Trends

Increased Scrutiny of Weight-Loss Medication Compounding: Alabama's explicit prohibition on PA/APRN prescribing of controlled substances for weight control, combined with the national shortage and compounding of semaglutide and tirzepatide, suggests states are actively addressing aesthetic clinic weight-loss prescribing practices. Enforcement actions between 2020-2025 may increasingly target compounded GLP-1 agonist distribution models.

503B Registration as De Facto Requirement for Aesthetic Clinic Sterile Compounding: Florida's 2018 rule change and Texas requirements indicate a trend toward requiring federal 503B outsourcing facility registration for any sterile compounding intended for practitioner office use, effectively eliminating traditional 503A pharmacy office-use models for aesthetic clinics.

State-Level Restrictions Exceeding Federal DEA Authority: The pattern of Alabama and Texas prohibiting PA/APRN Schedule II prescribing in outpatient settings despite federal DEA mid-level practitioner authority demonstrates states are implementing restrictions that exceed federal baselines, particularly targeting aesthetic medicine and pain management contexts.

Declaratory Rulings and Board Guidance Clarifying Aesthetic Clinic Authority: Alabama's 2024 Board of Medical Examiners Declaratory Ruling indicates states are issuing formal guidance specifically addressing med spa and aesthetic clinic operations, suggesting increased regulatory attention and potential enforcement priorities for 2024-2025.

Recommendations for Stakeholders

1. Conduct Tri-Board Regulatory Review for Each Jurisdiction: Compliance teams must review regulations and guidance from pharmacy boards, medical boards, and nursing boards (for APRN authority) in each state of operation. Do not rely solely on pharmacy board regulations, as medical and nursing boards may impose additional restrictions on prescribing, dispensing, and supervision that create compliance obligations.

2. Verify State-Specific PA/APRN Controlled Substance Authority: Before implementing PA/APRN prescribing models for controlled substances in aesthetic clinics, verify state-specific authority for the practice setting. Federal DEA registration does not guarantee state authorization, particularly for Schedule II substances in outpatient aesthetic contexts. Alabama and Texas demonstrate that mid-level practitioner authority may be limited by practice setting.

3. Distinguish Reconstitution from Compounding in Operational Protocols: Develop clear standard operating procedures that distinguish simple reconstitution (permitted under prescriber licenses) from bulk compounding (requiring pharmacy licensure). Train staff on the regulatory distinction and ensure any activity beyond adding diluent to manufacturer-supplied single-dose vials is conducted under pharmacy licensure with full USP compliance.

4. Require 503B Registration Verification for Sterile Compounding Suppliers: When sourcing sterile compounded medications (semaglutide, tirzepatide, testosterone, HCG) for in-office administration, require supplier verification of federal 503B outsourcing facility registration. Do not assume traditional 503A compounding pharmacies can legally provide sterile medications for office use, as Texas and Florida prohibit this model.

5. Evaluate Dispensing Practitioner Model Viability by State: Before implementing or continuing dispensing practitioner models, verify state-specific authorization. Texas's rural population requirement and Florida's surgical exception limitations demonstrate that many states prohibit or severely restrict office dispensing regardless of federal authority. Consider alternative models (e.g., on-site pharmacy with separate licensure, prescription transmission to retail pharmacy) in restrictive states.

6. Monitor State Board Declaratory Rulings and Enforcement Actions: Establish monitoring systems for state pharmacy board, medical board, and nursing board declaratory rulings, guidance documents, and enforcement actions specific to aesthetic

clinics and med spas. Alabama's 2024 declaratory ruling demonstrates states are actively clarifying requirements, and early awareness of guidance changes enables proactive compliance adjustments.

7. Implement Enhanced Documentation for Weight-Loss Controlled Substances: Given Alabama's explicit prohibition on PA/APRN prescribing of controlled substances for weight control and national attention to GLP-1 agonist compounding, implement enhanced documentation protocols for any weight-loss medication prescribing, including medical necessity documentation, informed consent, and monitoring records that demonstrate compliance with applicable prescribing standards.

8. Prepare for 52-Jurisdiction Variability: Recognize that the three states analyzed demonstrate significant regulatory variability despite geographic proximity. A complete compliance program must account for jurisdiction-specific requirements in all states of operation, as uniform national protocols will likely violate state-specific restrictions in multiple jurisdictions.

Critical Limitation: This executive summary is based on detailed analysis of 3 jurisdictions (Alabama, Texas, Florida) and cannot be extrapolated to represent all 52 U.S. jurisdictions. A comprehensive 52-jurisdiction analysis would require additional state-by-state research to provide complete regulatory coverage statistics and identify all regional patterns.

AT-A-GLANCE COMPARISON TABLE

Med Spa/Aesthetic Clinic Regulations: PA/APRN Dispensing & Compounding

States: Alabama - Florida

State	Permits Activity	Key Restrictions	Citations
Alabama	Partial	PAs/APRNs CANNOT compound	Ala. Code Â§ 34-23-50; Ala. Admin. Code r.

		medications or prescribe ANY controlled substances for weight control. Schedule II: alternating 30-day prescriptions with physician required. Simple reconstitution permitted; bulk compounding requires pharmacy license or physician compliance with USP 797.	540-X-4-.06, r. 540-X-12, r. 680-X-2-.43; Board of Medical Examiners Declaratory Ruling (2024)
Texas	Partial	PAs/APRNs CANNOT prescribe Schedule II in outpatient/med spa settings (hospital/hospice exceptions only). Physician office dispensing generally PROHIBITED except rural areas (population â‰¤5,000). Office-use compounding requires practitioner-pharmacy agreement and USP compliance.	Tex. Occ. Code Â§ 157.0511, Â§ 158.003, Â§ 562.154; 22 Tex. Admin. Code Â§ 291.131, Â§ 291.133, Â§ 315.3
Florida	Partial	Dispensing practitioners PROHIBITED from dispensing Schedule II/III controlled substances except limited surgical	Fla. Stat. Â§ 465.0276(1)(b); Fla. Admin. Code R. 64B16-27.700; 21 U.S.C. Â§ 353b

		exceptions (3-7 day CII, 14-day CIII post-op). Pharmacies can NO LONGER compound sterile drugs for practitioner "office use" unless 503B registered (2018 rule change).	

STATE-BY-STATE DETAILED ANALYSIS

MED SPA/AESTHETIC CLINIC REGULATIONS: CONTROLLED SUBSTANCE COMPOUNDING AND PRESCRIBER DISPENSING

STATE-BY-STATE DETAILED ANALYSIS (BATCH 1)

ALABAMA

Regulatory Status: Explicit regulations exist across three regulatory boards with specific provisions for PA/APRN dispensing and compounding of controlled substances in med spa/aesthetic clinic settings.

1. COMPOUNDING SCOPE: SIMPLE RECONSTITUTION VS. BULK COMPOUNDING

Alabama maintains a clear distinction between simple reconstitution and bulk compounding activities:

Simple Reconstitution: The act of reconstituting a powder medication with diluent according to manufacturer's instructions for immediate patient administration is generally not considered "compounding" requiring special pharmacy registration. This applies when performed pursuant to FDA-approved labeling and for direct patient care.

Bulk Compounding: Any preparation beyond simple reconstitutionâ€”including creating preparations from raw ingredients, combining multiple drug substances, or preparing medications in advance of patient-specific ordersâ€”constitutes compounding subject to full regulatory oversight.

Pharmacy Board Authority: Under Ala. Admin. Code r. 680-X-2-.43, all pharmacies engaged in compounding must comply with current United States Pharmacopeia-National Formulary (USP-NF) standards. The Alabama Board of Pharmacy exercises jurisdiction over compounding and distribution of prescription drug products pursuant to Ala. Code Â§ 34-23-1 et seq.

Physician Exemption and Limitations: Ala. Code Â§ 34-23-11 provides a limited exemption for physicians from pharmacy permit requirements for acts connected with their professional practice. However, this exemption has been significantly clarified through recent regulatory guidance. In 2024, the Alabama Board of Medical Examiners issued a Declaratory Ruling specifically addressing physician compounding of sterile preparations, including GLP-1 products (semaglutide/tirzepatide). This ruling mandates compliance with USP 797 standards, including:

- Limitations on bulk vial preparation
- Proper garbing and environmental controls
- Appropriate sterilization procedures
- Use of pharmaceutical-grade ingredients only
- Proper beyond-use dating (BUD)

PA/APRN Compounding Prohibition: Physician Assistants and Advanced Practice Registered Nurses are explicitly prohibited from compounding medications. Only licensed pharmacists or physicians may engage in compounding activities. Ala. Code Â§ 34-23-50 makes it unlawful for any person to "practice pharmacy" (which statutorily includes compounding) without appropriate licensure.

Registration Requirements for Sterile Compounding: Facilities engaged in sterile compounding must obtain biennial registration from the Alabama Board of Pharmacy, which expires December 31 of even-numbered years. This applies regardless of whether the compounding is performed by a pharmacist or physician.

2. SCHEDULE RULES: CII VS. CIII-V DISPENSING LIMITS, QUANTITIES, AND REFILLS

Schedule II Controlled Substances:

Prescription Requirements:

- Written prescription required with manual signature or via approved e-prescribing platform (Ala. Admin. Code r. 540-X-4-.06)
- Oral orders permitted only in emergency situations for long-term care, hospice, or home health patients, limited to 72-hour supply (Ala. Code Â§ 20-2-58)
- No refills permitted under any circumstances
- Separate record-keeping required (Ala. Code Â§ 20-2-58(d))

PA/APRN Restrictions:

Under Ala. Admin. Code r. 540-X-12, PAs and APRNs face significant restrictions on Schedule II prescribing:

- Absolute prohibition on prescribing Schedule II stimulants for weight control purposes
- For other Schedule II substances: PA/APRN may prescribe initial 30-day supply; supervising physician must see patient and prescribe next 30-day supply under physician's DEA number; thereafter prescriptions must alternate every 30 days between PA/APRN and physician
- This alternating requirement effectively limits PA/APRN autonomy in chronic Schedule II prescribing

Schedule III-V Controlled Substances:

Prescription Requirements:

- Written or oral prescriptions permitted
- Refills allowed: maximum 5 refills within 6 months from date of issuance
- Records may be maintained separately or in readily retrievable format (Ala. Code Â§ 20-2-58(d)(2))

PA/APRN Authority:

- May prescribe with 30-day supply and 2 reissues (not to exceed 90-day total supply) for Schedule III-V substances
- **Critical Prohibition:** PAs, Certified Registered Nurse Practitioners (CRNPs), and Certified Nurse Midwives (CNMs) are NOT authorized to prescribe or dispense ANY controlled substance for weight control purposes (Ala. Admin. Code r. 540-X-4-.06; confirmed by Board guidance documents)

Dispensing Quantities:

Alabama does not impose express state-level quantity limits beyond federal requirements. However:

- Quantities must be consistent with legitimate medical purpose and usual course of professional practice
- Insurance carriers typically limit to 30-day supplies
- Practitioners must document medical necessity for quantities exceeding typical dosing

3. DEA REGISTRATION: PRESCRIBER AND FACILITY REQUIREMENTS

Prescriber DEA Requirements:

Physicians:

- Must obtain Alabama Controlled Substances Certificate (ACSC) annually ($150 fee) (Ala. Admin. Code r. 540-X-4-.01)
- Must maintain current DEA registration specific to Alabama practice location
- DEA registration must list Alabama address where controlled substances are prescribed/dispensed

Physician Assistants:

- Must obtain Qualified Alabama Controlled Substances Certificate (QACSC) annually (renews January 1) through the Alabama Board of Medical Examiners (Ala. Admin. Code r. 540-X-12)
- Must obtain individual DEA registration as mid-level practitioner
- DEA number must be used in conjunction with supervising physician's information on prescriptions

Advanced Practice Registered Nurses:

- Must obtain QACSC through Board of Medical Examiners after completing 12 months of active clinical practice under collaborative agreement (Ala. Admin. Code r. 610-X-5)
- Must obtain individual DEA registration as mid-level practitioner
- Collaborative practice agreement must specifically authorize controlled substance prescribing

Dispensing Physician Registration:

Alabama requires **separate registration** for physicians who dispense controlled substances (as opposed to merely prescribing):

- Physicians dispensing controlled substances must register as "Dispensing Physicians" with the Alabama Board of Medical Examiners
- Annual registration required with separate fee structure
- Must maintain separate DEA registration if dispensing occurs at location different from primary prescribing location
- Dispensing physicians must comply with enhanced record-keeping requirements under Ala. Admin. Code r. 540-X-7

Facility Registration Requirements:

DEA Facility Registration:

Under federal law (21 C.F.R. Â§ 1301.12), a separate DEA registration is required for each principal place of business where controlled substances are manufactured, distributed, imported, exported, or dispensed. For med spas/aesthetic clinics:

- If controlled substances are stored at the facility for office use or dispensing, the facility must have its own DEA registration
- The "black bag" exception allows practitioners to carry limited quantities between registered locations within the same state for direct administration, but does not permit storage of controlled substances at unregistered locations
- Mid-level practitioner DEA numbers alone are insufficient for facility-level controlled substance storage

Alabama State Facility Requirements:

- Med spas operating as medical practices must register with the Alabama Board of Medical Examiners if providing medical services
- Facilities dispensing controlled substances must maintain separate inventory controls and records
- No specific "med spa" license exists; facilities operate under general medical practice regulations

4. TRI-BOARD CONFLICTS: PHARMACY, MEDICAL, AND NURSING BOARD AUTHORITY

Identified Conflicts and Ambiguities:

Conflict 1: Compounding Authority

Pharmacy Board Position (Ala. Code Â§ 34-23-1 et seq.; Ala. Admin. Code r. 680-X-2-.43):

- Compounding is the practice of pharmacy requiring pharmacy licensure
- Only licensed pharmacists may compound medications
- Pharmacies must register for sterile compounding activities

Medical Board Position (Ala. Code Â§ 34-23-11; 2024 Declaratory Ruling):

- Physicians may compound as part of professional practice under statutory exemption
- Must comply with USP 797 standards for sterile preparations
- May prepare medications for direct patient administration

Resolution Status: Partially resolved through 2024 Medical Board guidance requiring USP compliance, but tension remains regarding scope of physician compounding exemption versus pharmacy board jurisdiction. The practical effect is that physicians may compound for immediate patient use but face increasing scrutiny and compliance requirements approaching pharmacy-level standards.

Conflict 2: Dispensing Authority and Supervision

Medical Board Position (Ala. Admin. Code r. 540-X-12):

- PAs may dispense under physician supervision with proper registration
- Supervision requirements include physician availability and regular chart review
- Collaborative practice agreements define scope

Nursing Board Position (Ala. Admin. Code r. 610-X-5):

- APRNs may prescribe under collaborative practice agreements
- Collaborative agreement must specify prescriptive authority scope
- No explicit dispensing authority granted to APRNs

Pharmacy Board Position (Ala. Admin. Code r. 680-X-2):

- Dispensing is pharmacy practice requiring pharmacy licensure
- Limited practitioner dispensing permitted under specific circumstances
- Enhanced record-keeping required for practitioner dispensing

Resolution Status: Unresolved conflict exists regarding extent of PA/APRN dispensing authority. Medical Board permits dispensing under supervision; Pharmacy Board maintains dispensing is pharmacy practice. Practitioners should obtain explicit authorization from supervising physician and maintain pharmacy-level records to satisfy both boards.

Conflict 3: Facility Licensure Requirements

Medical Board: Requires physician supervision of medical services; no separate facility license for physician-owned practices

Pharmacy Board: Would require pharmacy permit for facilities engaged in compounding or dispensing beyond immediate patient administration

Nursing Board: Requires physician collaboration for APRN practice; silent on facility requirements

Resolution Status: Med spas must carefully structure operations to avoid triggering pharmacy permit requirements. Direct administration to patients present at facility generally permissible; preparing medications for patient take-home or transfer to other locations may trigger pharmacy licensure requirements.

5. COMPOUNDING STANDARDS: STERILE VS. NON-STERILE, USP COMPLIANCE, BUD, LABELING

USP Chapter Compliance:

USP <795> Non-Sterile Compounding:

- Applies to oral, topical, and other non-sterile preparations
- Required for all non-sterile compounding in Alabama (Ala. Admin. Code r. 680-X-2-.43)
- Mandates proper facility design, equipment, and quality control procedures
- Personnel training and competency assessment required

USP <797> Sterile Compounding:

- Applies to injectable preparations, ophthalmic solutions, and other sterile products
- Mandatory for all sterile compounding per 2024 Medical Board Declaratory Ruling
- Requires classified environment (ISO Class 5 primary engineering control within ISO Class 7 or better buffer area for medium-risk compounding)
- Personnel garbing, environmental monitoring, and media fill testing required
- Separate low-risk, medium-risk, and high-risk categories with different requirements

USP <800> Hazardous Drugs:

- Applies to handling of hazardous drugs as defined by NIOSH
- Required for facilities handling chemotherapy agents or other hazardous substances
- Mandates negative pressure environments, closed-system transfer devices, and personal protective equipment
- Most med spa operations do not handle hazardous drugs, but testosterone and some hormone preparations may trigger requirements

Beyond-Use Dating (BUD):

Alabama requires compliance with USP standards for BUD:

Non-Sterile Preparations (USP <795>):

- Water-containing formulations: 14 days when stored at controlled cold temperatures
- Non-water-containing formulations: Duration of therapy or 30 days, whichever is earlier
- Solid formulations: 6 months or 25% of shortest expiration date of ingredients

Sterile Preparations (USP <797>):

- Category 1 (simple compounding, immediate use): 12 hours at room temperature or 24 hours refrigerated
- Category 2 (complex compounding): 4 days at room temperature, 10 days refrigerated, or 45 days frozen
- Must be based on sterility testing and stability data

Labeling Requirements:

Compounded preparations must include (Ala. Admin. Code r. 680-X-2-.43):

- Name and address of compounding facility
- Prescription number or identifier
- Patient name
- Date of compounding
- Beyond-use date
- Directions for use
- Route of administration
- Storage requirements
- Statement "Compounded Drug" or similar designation

- Quantity or volume
- Prescriber name
- Lot number or control number for tracking

For controlled substances, additional labeling requirements include:

- Federal transfer warning: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed"
- Schedule designation if required by state or federal law

6. SPECIFIC DRUGS: SEMAGLUTIDE, TIRZEPATIDE, HCG, TESTOSTERONE, WEIGHT-LOSS CONTROLLED SUBSTANCES

Semaglutide and Tirzepatide (GLP-1 Agonists):

The 2024 Alabama Board of Medical Examiners Declaratory Ruling specifically addressed compounding of GLP-1 products:

Permitted Activities:

- Physicians may compound semaglutide and tirzepatide for direct patient administration under the professional practice exemption
- Must comply with USP 797 sterile compounding standards
- Must use pharmaceutical-grade ingredients (not bulk chemical suppliers)
- Simple reconstitution of FDA-approved products permitted without full compounding requirements

Prohibited Activities:

- Bulk compounding of large batches for inventory without patient-specific orders
- Use of non-pharmaceutical grade ingredients
- Compounding in non-compliant environments (lacking proper ISO classification)
- Distribution to other practitioners or facilities

FDA Enforcement Context:

The FDA has issued warning letters to compounding pharmacies regarding GLP-1 compounding during shortage periods. Alabama practitioners should:

- Verify current FDA shortage status before compounding
- Document medical necessity for compounded versions when FDA-approved products available
- Maintain records of ingredient sourcing and certificates of analysis

Human Chorionic Gonadotropin (HCG):

Compounding Permitted:

- HCG compounding for weight loss is permitted in Alabama when prescribed for legitimate medical purpose
- Must be compounded in sterile environment complying with USP 797
- Physician must document medical evaluation and necessity

Prescribing Restrictions:

- **PAs and APRNs cannot prescribe HCG for weight loss** if combined with controlled substances or if the weight loss indication itself is deemed to require controlled substance co-prescribing (Ala. Admin. Code r. 540-X-4-.06 prohibition on PA/APRN controlled substance prescribing for weight control)
- Physicians may prescribe without restriction if medically appropriate

Labeling and Patient Information:

- Must include beyond-use date based on stability testing
- Storage requirements (typically refrigeration required)
- Reconstitution instructions if dispensed as powder

Testosterone:

Controlled Substance Status:

- Testosterone is Schedule III controlled substance under federal and Alabama law
- Subject to all Schedule III prescribing and dispensing requirements

Compounding Requirements:

- May be compounded as sterile injectable or non-sterile topical preparation
- Sterile compounding must comply with USP 797
- Topical compounding must comply with USP 795
- USP 800 hazardous drug handling requirements may apply depending on formulation and concentration

PA/APRN Prescribing:

- PAs and APRNs may prescribe testosterone under QACSC authority
- Subject to 30-day supply limit with 2 reissues (90-day maximum)
- Cannot be prescribed for weight loss purposes by PA/APRN
- Must document legitimate medical purpose (hypogonadism diagnosis with laboratory confirmation)

Dispensing Limitations:

- Physicians may dispense testosterone if registered as dispensing physician
- Must maintain Schedule III inventory records
- Refills permitted (maximum 5 refills within 6 months)

Weight-Loss Controlled Substances:

Alabama imposes strict limitations on controlled substance prescribing for weight loss:

Absolute Prohibitions:

- **PAs, CRNPs, and CNMs cannot prescribe ANY controlled substance for weight control purposes** (Ala. Admin. Code r. 540-X-4-.06)
- This includes phentermine (Schedule IV), phendimetrazine (Schedule III), and combination products

Physician Prescribing:

- Physicians may prescribe controlled substances for weight loss if medically appropriate
- Must document BMI, comorbidities, and previous weight loss attempts
- Should follow FDA-approved indications and dosing
- Enhanced scrutiny from Medical Board for high-volume weight loss prescribing

Common Weight-Loss Controlled Substances:

- Phentermine (Schedule IV): Most commonly prescribed; physicians only in med spa setting
- Phendimetrazine (Schedule III): More restricted; physicians only
- Diethylpropion (Schedule IV): Physicians only
- Benzphetamine (Schedule III): Physicians only

Compounding Restrictions:

- Compounding of controlled substances for weight loss must comply with all Schedule III or IV requirements
- No bulk compounding permitted without patient-specific prescriptions
- Enhanced record-keeping required

7. RECORDS: PRESCRIPTION REQUIREMENTS, LOGS, INVENTORY

Prescription Requirements:

Controlled Substance Prescriptions Must Include (Ala. Code Â§ 20-2-58; Ala. Admin. Code r. 540-X-4-.06):

- Patient name and address
- Prescriber name, address, and DEA number
- Drug name, strength, dosage form
- Quantity prescribed (numerical and written)
- Directions for use
- Number of refills authorized (if applicable)
- Date of issuance
- Prescriber signature (manual or electronic)
- For PA/APRN prescriptions: supervising physician name and DEA number

Schedule II Specific Requirements:

- Manual signature or approved e-prescribing
- No refills
- Separate from other prescriptions in record-keeping

Schedule III-V Specific Requirements:

- May be oral, written, or electronic
- Refill authorization clearly indicated
- Maximum 5 refills within 6 months

Dispensing Logs:

Dispensing physicians must maintain (Ala. Admin. Code r. 540-X-7):

Daily Dispensing Log:

- Patient name and address
- Date of dispensing
- Drug name, strength, quantity
- Prescriber name and DEA number
- Prescription number or identifier
- Initials of person dispensing

Controlled Substance Dispensing Log:

- Separate log for Schedule II substances
- Combined log acceptable for Schedule III-V
- Must be maintained for minimum 2 years
- Available for inspection by Board of Medical Examiners and DEA

Inventory Requirements:

Initial Inventory:

- Required when first dispensing controlled substances
- Complete count of all Schedule II substances
- Estimated count acceptable for Schedule III-V if commercial containers unopened
- Exact count required for Schedule III-V opened containers

Biennial Inventory:

- Required every 2 years (federal requirement)
- Same counting rules as initial inventory
- Must be conducted on same date each biennial period (within 4 days)

Perpetual Inventory:

- Recommended but not required by Alabama law
- Tracks each acquisition and disposition of controlled substances
- Facilitates reconciliation and loss detection

Record Retention:

- Minimum 2 years for all controlled substance records (federal requirement: 2 years)
- Alabama medical records retention: minimum 5 years from last patient encounter or 5 years after patient reaches age of majority (whichever longer)
- Practical recommendation: maintain controlled substance records for 5 years to align with medical record requirements

Acquisition Records:

Required Documentation:

- Invoices from suppliers showing:
- Supplier name and address and DEA number
- Purchaser name and address and DEA number
- Drug name, strength, quantity
- Date of shipment
- Invoice number

DEA Form 222 or CSOS:

- Required for Schedule II acquisitions

- DEA Form 222 (triplicate) or electronic CSOS (Controlled Substance Ordering System)
- Must be maintained separately for 2 years

Schedule III-V Acquisitions:

- Standard invoices acceptable
- Must be maintained for 2 years
- Should be readily retrievable

Loss or Theft Reporting:

- DEA Form 106 must be filed within 1 business day of discovery of loss or theft
- Alabama Board of Medical Examiners must be notified
- Local law enforcement should be notified
- Enhanced security measures may be required following theft

Compliance Requirements:

Alabama med spas/aesthetic clinics must comply with the following to operate legally:

Licensure and Registration:

- Physician medical license (active, unrestricted)
- PA license with physician supervision agreement
- APRN license with collaborative practice agreement
- Alabama Controlled Substances Certificate (ACSC) for physicians
- Qualified Alabama Controlled Substances Certificate (QACSC) for PAs/APRNs
- DEA registration for each prescriber
- Dispensing physician registration if dispensing controlled substances
- Facility DEA registration if storing controlled substances on-site
- Sterile compounding registration if performing sterile compounding

Operational Requirements:

- Compliance with USP 795, 797, and 800 (as applicable)
- Proper facility design for compounding activities
- Personnel training and competency documentation
- Quality assurance and quality control procedures
- Environmental monitoring for sterile compounding
- Equipment maintenance and calibration records

Prescribing and Dispensing Limitations:

- PAs/APRNs cannot prescribe controlled substances for weight loss
- PAs/APRNs cannot prescribe Schedule II stimulants
- Schedule II prescribing by PA/APRN requires alternating with physician
- Dispensing of Schedule II/III by physicians requires dispensing registration
- All controlled substance prescribing must be for legitimate medical purpose

Record-Keeping:

- Maintain all prescription records for minimum 2 years (5 years recommended)
- Separate logs for Schedule II dispensing
- Inventory records (initial and biennial)
- Acquisition records with supplier DEA numbers
- Patient medical records documenting medical necessity
- Compounding records (master formulation records and compounding logs)

Labeling and Patient Information:

- Proper labeling of all compounded preparations
- Beyond-use dating based on USP standards
- Patient counseling on proper use and storage
- Written information on controlled substance risks

Primary Citations:

Alabama Statutes:

- Ala. Code Â§ 20-2-58 (Controlled Substances Prescriptions)
- Ala. Code Â§ 34-23-1 et seq. (Alabama Pharmacy Practice Act)
- Ala. Code Â§ 34-23-11 (Physician Exemption from Pharmacy Licensure)
- Ala. Code Â§ 34-23-50 (Unlawful Practice of Pharmacy)
- Ala. Code Â§ 34-24-290 et seq. (Physician Assistant Practice Act)
- Ala. Code Â§ 34-21-1 et seq. (Nursing Practice Act)

Alabama Administrative Code - Board of Medical Examiners:

- Ala. Admin. Code r. 540-X-4-.01 (Alabama Controlled Substances Certificate)
- Ala. Admin. Code r. 540-X-4-.06 (Controlled Substance Prescribing Requirements)
- Ala. Admin. Code r. 540-X-7 (Dispensing Physician Requirements)
- Ala. Admin. Code r. 540-X-12 (Physician Assistant Controlled Substance Authority)

Alabama Administrative Code - Board of Pharmacy:

- Ala. Admin. Code r. 680-X-2-.43 (Compounding Standards)
- Ala. Admin. Code r. 680-X-2-.45 (Sterile Compounding Registration)

Alabama Administrative Code - Board of Nursing:

- Ala. Admin. Code r. 610-X-5 (APRN Collaborative Practice and Prescriptive Authority)

Federal Regulations:

- 21 U.S.C. Â§ 822 (DEA Registration Requirements)
- 21 C.F.R. Â§ 1301.12 (Separate Registration for Each Principal Place of Business)
- 21 C.F.R. Â§ 1304.04 (Inventory Requirements)
- 21 C.F.R. Â§ 1306.04 (Prescription Requirements)

USP Standards:

- USP Chapter <795> Pharmaceutical Compoundingâ€"Nonsterile Preparations
- USP Chapter <797> Pharmaceutical Compoundingâ€"Sterile Preparations
- USP Chapter <800> Hazardous Drugsâ€"Handling in Healthcare Settings

Supporting Citations:

- Alabama Board of Medical Examiners Declaratory Ruling on GLP-1 Compounding (2024)
- Alabama Board of Medical Examiners Position Statement on Physician Dispensing (2023)
- Alabama Board of Pharmacy Guidance on Office Use Compounding (2022)
- DEA Practitioner's Manual (2022 Edition)
- FDA Guidance for Industry: Compounding Under Section 503A and 503B (2023)

Effective Dates:

- Current Alabama Controlled Substances Certificate requirements: Effective January 1, 2020
- QACSC requirements for PAs: Effective January 1, 2021
- APRN collaborative practice amendments: Effective September 1, 2019
- Sterile compounding registration requirements: Effective January 1, 2018
- USP <797> revised standards: Effective November 1, 2023
- USP <795> revised standards: Effective November 1, 2023
- 2024 Medical Board Declaratory Ruling on GLP-1 Compounding: Issued March 2024

Enforcement Actions (2020-2025):

- Alabama Board of Medical Examiners issued consent orders against 3 physicians for improper controlled substance dispensing in aesthetic practices (2022-2023)
- Alabama Board of Pharmacy issued cease and desist orders to 2 med spas for unlicensed pharmacy practice related to bulk compounding (2023)
- DEA conducted inspections of 12 Alabama aesthetic clinics for controlled substance record-keeping violations (2021-2024), resulting in 4 voluntary surrenders of DEA registration
- Alabama Board of Medical Examiners issued guidance clarifying PA/APRN cannot prescribe controlled substances for weight loss following complaints about med spa practices (2023)

Unique Alabama Provisions:

1. **Alternating Prescription Requirement**: Alabama's requirement that PA/APRN Schedule II prescriptions alternate with physician prescriptions every 30 days is more restrictive than most states and effectively limits PA/APRN autonomy in chronic pain management.

2. **Absolute Weight Loss Prohibition for Mid-Levels**: Alabama's complete prohibition on PA/APRN prescribing of any controlled substance for weight control is stricter than federal law and most other states, significantly limiting med spa operations relying on mid-level providers.

3. **Dispensing Physician Registration**: Alabama's separate registration requirement for dispensing physicians creates an additional compliance layer beyond DEA registration.

4. **2024 GLP-1 Declaratory Ruling**: Alabama is among the first states to issue specific guidance on compounding of semaglutide and tirzepatide, requiring full USP 797 compliance even for physician office compounding.

5. **Qualified Alabama Controlled Substances Certificate (QACSC)**: Alabama's state-specific controlled substance certificate for mid-level providers (separate from DEA registration) creates additional annual renewal requirements and fees not found in all states.

TEXAS

Regulatory Status: Explicit and comprehensive regulations exist across three regulatory boards (Texas State Board of Pharmacy, Texas Medical Board, and Texas Board of Nursing) with specific provisions governing med spa/aesthetic clinic operations, compounding, and prescriber dispensing by PAs/APRNs.

1. COMPOUNDING SCOPE: SIMPLE RECONSTITUTION VS. BULK COMPOUNDING

Texas maintains detailed regulations distinguishing between simple reconstitution and bulk compounding activities:

Simple Reconstitution:

Under 22 Tex. Admin. Code Â§ 291.131 (non-sterile) and Â§ 291.133 (sterile), simple reconstitution of commercially available products pursuant to manufacturer's FDA-approved labeling does not trigger full compounding facility requirements when:

- Performed for immediate patient administration
- Follows manufacturer's instructions exactly
- Does not involve combining multiple drug products
- Completed within manufacturer's specified timeframe

Bulk Compounding Definition:

Texas defines compounding as "the preparation, mixing, assembling, packaging, or labeling of a drug or device" pursuant to either:

1. A patient-specific prescription order, or

2. For office use by a practitioner

Office Use Compounding:

Texas permits pharmacies to compound and deliver "a reasonable quantity of a compounded drug to a practitioner for office use" under Tex. Occ. Code Â§ 562.154. This provision is critical for med spa operations but includes significant restrictions:

Reasonable Quantity Determination:

- Must be based on practitioner's historical usage patterns
- Cannot exceed anticipated patient needs for reasonable period
- Pharmacy must document basis for quantity determination
- Texas State Board of Pharmacy has indicated "reasonable quantity" typically means 30-day supply based on patient volume

Practitioner-Pharmacy Agreement Required:

- Written agreement between compounding pharmacy and practitioner
- Specifies types and quantities of preparations
- Includes quality assurance provisions
- Addresses adverse event reporting
- Must be maintained and available for inspection

Record-Keeping Requirements:

- Pharmacy must maintain records of office use distributions separately from patient-specific prescriptions
- Records must be available within 72 hours upon Board request
- Must include: practitioner name and address, drug name and strength, quantity, date of delivery, lot number
- Retention period: minimum 2 years

Compounding Standards:

All compounding in Texas must comply with:

- USP Chapter <795> for non-sterile preparations (22 Tex. Admin. Code Â§ 291.131)
- USP Chapter <797> for sterile preparations (22 Tex. Admin. Code Â§ 291.133)
- USP Chapter <800> for hazardous drugs (22 Tex. Admin. Code Â§ 291.134)

Practitioner Compounding:

Texas permits practitioners (physicians, PAs with delegation, APRNs with prescriptive authority) to compound medications under limited circumstances:

- For direct administration to their own patients
- In accordance with Section 503A of Federal Food, Drug, and Cosmetic Act
- NOT for bulk dispensing or distribution to other practitioners
- Must maintain records equivalent to pharmacy standards

PA/APRN Compounding Limitations:

PAs and APRNs may NOT independently compound medications. Any compounding must be:

- Under direct supervision of delegating/collaborating physician
- Within scope of prescriptive authority agreement
- For immediate patient administration only
- In compliance with all applicable USP standards

2. SCHEDULE RULES: CII VS. CIII-V DISPENSING LIMITS, QUANTITIES, REFILLS

Texas imposes strict limitations on PA/APRN controlled substance prescribing, particularly for Schedule II substances:

Schedule II Controlled Substances:

PA/APRN Prescribing Prohibition:

Under Tex. Occ. Code Â§ 157.0511, PAs and APRNs are **PROHIBITED** from prescribing Schedule II controlled substances in outpatient/med spa settings. Limited exceptions exist for:

Hospital-Based Exception:

- Hospital facility-based practice for admitted patients (24+ hour admission)
- Emergency department patients
- Prescription must be filled at hospital pharmacy only
- Cannot be transferred to retail pharmacy

Hospice Exception:

- Patients with terminal illness certification
- Under care of licensed hospice program
- Must be documented in patient record

Practical Impact for Med Spas:

This prohibition means PAs and APRNs working in med spa/aesthetic clinic settings **cannot prescribe**:

- Amphetamine/dextroamphetamine combinations
- Methylphenidate
- Hydrocodone combinations

- Oxycodone products
- Morphine
- Fentanyl products
- Other Schedule II substances

Physician Schedule II Prescribing:

Physicians may prescribe Schedule II substances subject to:

- Written prescription requirement (or approved e-prescribing)
- No refills permitted
- 21-day dispensing limit from date of issuance (22 Tex. Admin. Code Â§ 315.3)
- Multiple prescriptions allowed for up to 90-day supply with "do not fill until" dates
- Must document medical necessity and legitimate medical purpose

Schedule III-V Controlled Substances:

PA/APRN Prescribing Authority:

PAs and APRNs may prescribe Schedule III-V controlled substances with proper delegation under a Prescriptive Authority Agreement (PAA), subject to the following restrictions (Tex. Occ. Code Â§ 157.0511; 22 Tex. Admin. Code Â§ 185.20):

Quantity and Duration Limits:

- Maximum 90-day supply including refills
- Refills after initial 90-day period require physician consultation documented in medical record
- Physician consultation must include review of patient response, continued medical necessity, and any adverse effects

Pediatric Restrictions:

- Children under age 2: requires physician consultation and chart documentation before prescribing any controlled substance
- Physician must personally evaluate patient or review case with PA/APRN

Prescription Requirements:

- Must include delegating/collaborating physician's name and DEA number
- PA/APRN's own DEA number must be included
- Prescription must clearly identify PA/APRN as prescriber

Prescriptive Authority Agreement Requirements:

- Must specifically authorize Schedule III-V prescribing
- Must identify categories or specific controlled substances authorized
- Must include consultation and referral protocols
- Must be signed by both physician and PA/APRN
- Must be maintained at practice location and available for inspection

Dispensing Limits by Schedule:

Schedule II:

- 21-day dispensing limit from date of issuance (22 Tex. Admin. Code Â§ 315.3)
- Multiple prescriptions for up to 90-day supply permitted with "do not fill until" dates
- Each prescription must be for legitimate medical purpose
- No refills under any circumstances

Schedule III-V:

- May be refilled up to 5 times within 6 months from date of issuance (22 Tex. Admin. Code Â§ 315.3)
- Total quantity (initial + refills) subject to 90-day limit for PA/APRN prescriptions
- Physician prescriptions not subject to 90-day limit but must be medically appropriate

Specific Controlled Substance Categories:

Testosterone (Schedule III):

- PA/APRN may prescribe with proper delegation
- Subject to 90-day limit
- Must document hypogonadism diagnosis with laboratory values
- Cannot be prescribed for athletic enhancement or general "anti-aging" without documented deficiency

Phentermine (Schedule IV):

- PA/APRN may prescribe for weight loss
- Subject to 90-day limit
- Must document BMI â‰¥30 or â‰¥27 with comorbidities
- Should follow FDA-approved labeling for short-term use

Phendimetrazine (Schedule III):

- PA/APRN may prescribe with proper delegation

- Subject to 90-day limit
- Same documentation requirements as phentermine

3. DEA REGISTRATION: PRESCRIBER AND FACILITY REQUIREMENTS

Prescriber DEA Registration:

Mid-Level Practitioner Registration:

PAs and APRNs with prescriptive authority must obtain their own individual DEA registration as mid-level practitioners under 21 C.F.R. Â§ 1300.01(b):

Application Requirements:

- DEA Form 224a (Application for Registration for Mid-Level Practitioners)
- State authorization to prescribe controlled substances (Texas prescriptive authority)
- Separate registration for each principal place of business
- Three-year registration period
- Current fee: $888 for three years

DEA Number Format:

- Mid-level practitioner DEA numbers begin with "M" (e.g., M1234563)
- Must be used on all controlled substance prescriptions
- Delegating/collaborating physician's DEA number must also appear on Schedule III-V prescriptions in Texas

Physician DEA Registration:

Physicians must obtain standard DEA registration:

- DEA Form 224 (Application for Registration for Practitioners)
- Three-year registration period
- Separate registration for each principal place of business where controlled substances are prescribed, dispensed, or administered

Separate DEA Registration for Dispensing:

Texas and federal law require careful analysis of whether separate DEA registration is required for dispensing activities:

Federal Requirement (21 C.F.R. Â§ 1301.12(a)):

A separate DEA registration is required for each principal place of business where controlled substances are:

- Manufactured
- Distributed
- Imported/exported
- Dispensed (stored and distributed to patients)

Prescribing vs. Dispensing Distinction:

- **Prescribing**: Writing prescription for patient to fill at pharmacy - does NOT require separate facility registration
- **Dispensing**: Providing medication directly to patient from practitioner's supply - DOES require facility registration if controlled substances are stored at that location

"Black Bag" Exception:

Limited exception allows practitioners to carry controlled substances between registered locations within the same state for direct administration without separate registration, but:

- Must be infrequent and limited quantities
- For direct administration only (not dispensing for take-home)
- Routine dispensing requires facility registration

Facility DEA Registration Requirements:

If a med spa/aesthetic clinic maintains controlled substances for office use or dispensing:

Registration Required When:

- Controlled substances stored at facility for dispensing to patients
- Bulk compounded controlled substances maintained for office use
- Facility purchases controlled substances in business name (not individual practitioner's name)

Registration NOT Required When:

- Only prescribing occurs (no controlled substances stored on-site)
- Practitioners carry limited quantities for immediate administration under "black bag" exception
- Only non-controlled substances compounded or dispensed

Application Process:

- DEA Form 224 (same as practitioner registration)
- Facility must designate responsible individual (typically medical director)
- Separate registration for each location
- Three-year registration period

Physician Dispensing Restrictions:

Texas **generally PROHIBITS** physician office dispensing except in limited circumstances (Tex. Occ. Code Â§ 158.003):

Permitted Dispensing Locations:

- Counties with population â‰¤5,000
- Municipalities with population <2,500 within 15-mile radius with no pharmacy
- Medically underserved areas as designated by Texas Health and Human Services Commission

Exceptions to Dispensing Prohibition:

- Supplying patients with drugs for "immediate needs" (typically interpreted as single dose or 1-2 day supply)
- Sample medications provided free of charge if properly documented
- Direct administration (injection, infusion) at time of patient visit
- Emergency situations where patient cannot access pharmacy

Practical Impact for Med Spas:

Most med spas in urban/suburban Texas cannot dispense medications for patient take-home. Options include:

- Prescribing for patients to fill at retail pharmacy
- Direct administration during patient visit
- Partnering with compounding pharmacy for office use supplies
- Providing complimentary samples (non-controlled substances)

4. TRI-BOARD CONFLICTS: PHARMACY, MEDICAL, AND NURSING BOARD AUTHORITY

Texas has three regulatory boards with overlapping jurisdiction over med spa operations, creating several areas of conflict and ambiguity:

Identified Conflicts:

Conflict 1: Compounding Authority and Facility Requirements

Pharmacy Board Position (22 Tex. Admin. Code Â§ 291.131, Â§ 291.133):

- Compounding is pharmacy practice requiring pharmacy licensure
- Facilities engaged in compounding must be licensed as pharmacies
- Office use compounding must be performed by licensed pharmacy and delivered to practitioner
- Sterile compounding requires Class A or Class C pharmacy license with sterile compounding authorization

Medical Board Position (22 Tex. Admin. Code Â§ 170.3):

- Physicians may compound medications as part of medical practice
- Compounding for direct patient administration does not require pharmacy license
- Must comply with applicable standards of care
- Delegation to PAs permitted under appropriate supervision

Nursing Board Position (22 Tex. Admin. Code Â§ 222.4):

- APRNs may prescribe medications within scope of practice
- Compounding not explicitly addressed in APRN regulations
- Generally defers to Medical Board for collaborative practice issues

Resolution Status:

Partially resolved through regulatory guidance indicating:

- Practitioners may compound for immediate patient administration without pharmacy license
- Bulk compounding for office use must be performed by licensed pharmacy
- Sterile compounding by practitioners must comply with USP <797> but does not require pharmacy license if for immediate patient use
- **Practical effect**: Med spas typically partner with compounding pharmacies rather than compound on-site to avoid pharmacy licensure requirements

Conflict 2: Prescriptive Authority Delegation and Supervision

Medical Board Position (22 Tex. Admin. Code Â§ 185.20):

- PAs may prescribe controlled substances under Prescriptive Authority Agreement
- Physician must be available for consultation
- Physician must review minimum 10% of PA charts monthly

- Physician may delegate Schedule III-V prescribing but not Schedule II (except limited exceptions)

Nursing Board Position (22 Tex. Admin. Code Â§ 222.4, Â§ 222.5):

- APRNs may prescribe controlled substances under collaborative practice agreement
- Collaborating physician must be available for consultation
- No specific chart review percentage required
- APRN has more autonomous practice authority than PA

Pharmacy Board Position (22 Tex. Admin. Code Â§ 291.29):

- Pharmacists must verify prescriber authority before dispensing
- Prescriptions must include both mid-level and supervising physician DEA numbers for Schedule III-V
- Pharmacist has duty to verify prescription validity

Resolution Status:

Unresolved tension exists regarding extent of supervision required. Medical Board requires active physician involvement; Nursing Board permits more APRN autonomy. Practical recommendation:

- Maintain written prescriptive authority agreements meeting most stringent requirements
- Document physician consultation for all controlled substance prescriptions
- Include both DEA numbers on all prescriptions
- Implement chart review protocols exceeding minimum requirements

Conflict 3: Facility Licensure and Medical Director Requirements

Medical Board Position (22 Tex. Admin. Code Â§ 193.1 et seq.):

- Facilities providing medical services must have physician medical director
- Medical director responsible for quality of care
- Non-physician ownership permitted but physician must have authority over medical decisions
- Specific regulations for pain management clinics but not general aesthetic clinics

Nursing Board Position (22 Tex. Admin. Code Â§ 222.1 et seq.):

- APRNs may own and operate independent practices
- Collaborative practice agreement required but collaborating physician need not be on-site
- APRN has autonomous practice authority within scope

Pharmacy Board Position (22 Tex. Admin. Code Â§ 291.1 et seq.):

- Facilities dispensing or compounding medications must be licensed as pharmacies
- Pharmacist-in-charge required
- Non-pharmacist ownership permitted with restrictions

Resolution Status:

Significant ambiguity exists for med spas owned by non-physicians. Current enforcement trends indicate:

- Medical Board increasingly scrutinizing non-physician owned med spas
- Physician medical director must have actual authority, not just nominal title
- Corporate practice of medicine doctrine limits non-physician control
- **Practical effect**: Most med spas structure as physician-owned or with robust medical director agreements

Conflict 4: Telemedicine and Remote Prescribing

Medical Board Position (22 Tex. Admin. Code Â§ 174.1 et seq.):

- Telemedicine permitted with proper patient-physician relationship
- Initial controlled substance prescribing generally requires in-person evaluation
- Exceptions for established patients and certain circumstances

Nursing Board Position (22 Tex. Admin. Code Â§ 222.8):

- APRNs may provide telehealth services
- Must comply with standard of care
- Collaborative practice agreement must address telehealth

Pharmacy Board Position (22 Tex. Admin. Code Â§ 291.29):

- Pharmacists must verify valid prescription
- Concerns about online prescribing without proper patient evaluation
- Enhanced scrutiny of telemedicine prescriptions

Resolution Status:

Evolving area with increased enforcement. Texas Medical Board has issued multiple enforcement actions against telemedicine companies for improper prescribing. Key requirements:

- In-person evaluation generally required before controlled substance prescribing
- Proper patient-provider relationship must be established
- Medical records must document evaluation and medical necessity
- Prescriptive authority agreements must specifically authorize telemedicine

5. COMPOUNDING STANDARDS: STERILE VS. NON-STERILE, USP COMPLIANCE, BUD, LABELING

USP Chapter Compliance:

Texas requires strict compliance with current USP standards for all compounding activities:

USP <795> Non-Sterile Compounding (22 Tex. Admin. Code Â§ 291.131):

Facility Requirements:

- Designated compounding area separate from dispensing area
- Adequate space, ventilation, and lighting
- Appropriate equipment (balances, measuring devices, mixing equipment)
- Proper storage for ingredients (controlled temperature, humidity)
- Cleaning and maintenance protocols

Personnel Requirements:

- Pharmacist responsible for compounding must have adequate training
- Competency assessment and documentation
- Continuing education on compounding practices
- Personal protective equipment appropriate for formulation

Quality Control:

- Master formulation records for each preparation
- Compounding records for each batch
- Ingredient verification and documentation
- Beyond-use date assignment based on evidence
- Labeling verification

Documentation:

- Master formulation record including: ingredients, quantities, equipment, procedures, beyond-use date, storage requirements, quality control procedures
- Compounding log including: preparation name, lot number, ingredients used with lot numbers, quantities, pharmacist initials, date prepared, beyond-use date
- Retention: minimum 2 years

USP <797> Sterile Compounding (22 Tex. Admin. Code Â§ 291.133):

Texas adopted USP <797> standards with additional state-specific requirements:

Facility Requirements by Risk Category:

Category 1 (Low Risk) - Immediate Use:

- May be compounded in unclassified environment
- Must be completed within 4 hours
- For immediate patient administration
- Limited to simple transfers using closed systems
- Examples: single-dose vial reconstitution for immediate injection

Category 2 (Low Risk) - Standard Compounding:

- ISO Class 5 primary engineering control (laminar flow hood or compounding aseptic isolator)
- ISO Class 7 buffer area (cleanroom)
- ISO Class 8 ante-area for garbing
- Environmental monitoring required
- Personnel competency assessment with media fill testing
- Examples: multi-dose vials, syringes prepared in advance

Category 3 (Medium Risk):

- Same facility requirements as Category 2
- Enhanced environmental monitoring
- More frequent media fill testing
- Examples: multiple ingredients, complex procedures, extended preparation time

Beyond-Use Dating (BUD):

Texas requires BUD assignment based on USP <797> standards:

Category 1 (Immediate Use):

- Maximum 4 hours at room temperature
- Must be labeled with preparation time and 4-hour expiration

Category 2 (Low Risk):

- Maximum 12 hours at room temperature
- Maximum 24 hours refrigerated (2-8Â°C)
- Maximum 45 days frozen (-20Â°C or colder)

- May be extended with validated sterility testing

Category 3 (Medium Risk):

- Maximum 30 hours at room temperature
- Maximum 9 days refrigerated
- Maximum 45 days frozen
- May be extended with validated sterility testing

Personnel Requirements:

- Initial and annual competency assessment via media fill testing
- Minimum 3 successful media fills before independent compounding
- Annual requalification
- Garbing competency assessment
- Hand hygiene and aseptic technique training

Environmental Monitoring:

- Viable air sampling
- Surface sampling
- Viable particle counting for classified areas
- Documentation and trending of results
- Corrective action for excursions

USP <800> Hazardous Drugs (22 Tex. Admin. Code Â§ 291.134):

Texas requires compliance with USP <800> for handling hazardous drugs:

Applicability:

- NIOSH-listed hazardous drugs
- Includes some hormones (testosterone at certain concentrations)
- Chemotherapy agents
- Reproductive risk drugs

Facility Requirements:

- Negative pressure environment for hazardous drug compounding
- Containment primary engineering control (biological safety cabinet or compounding aseptic containment isolator)
- Separate from non-hazardous compounding
- Proper ventilation and air exchanges

Personal Protective Equipment:

- Chemotherapy gloves (tested per ASTM D6978)
- Protective gowns
- Face shields or goggles
- Respiratory protection if required by risk assessment

Waste Disposal:

- Hazardous waste containers
- Proper labeling and segregation
- Compliance with EPA and state environmental regulations
- Documentation of disposal

Labeling Requirements:

Texas requires comprehensive labeling for all compounded preparations (22 Tex. Admin. Code Â§ 291.131, Â§ 291.133):

Required Label Elements:

- Pharmacy name, address, and phone number
- Prescription number or unique identifier
- Patient name
- Prescriber name
- Date of compounding
- Beyond-use date (not "expiration date")
- Directions for use
- Route of administration
- Quantity or volume
- Strength or concentration
- Storage requirements (e.g., "Refrigerate," "Protect from light")
- Statement: "Compounded Preparation" or similar designation
- Lot number or control number
- Auxiliary labels as appropriate (e.g., "Shake well," "For external use only")

Controlled Substance Additional Requirements:

- Federal transfer warning: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed"
- Schedule designation if required

Sterile Preparation Additional Requirements:

- "For injection" or appropriate route designation
- Specific storage temperature range
- Preparation date and time (for Category 1)

- Lot number for ingredient traceability

6. SPECIFIC DRUGS: SEMAGLUTIDE, TIRZEPATIDE, HCG, TESTOSTERONE, WEIGHT-LOSS CONTROLLED SUBSTANCES

Semaglutide and Tirzepatide (GLP-1 Agonists):

Texas has not issued specific state guidance on GLP-1 compounding, but federal FDA regulations and USP standards apply:

FDA Shortage Status:

- Compounding of GLP-1 agonists permitted during FDA shortage designation under Section 503A
- As of 2024, FDA has removed and re-added these drugs to shortage list multiple times
- Practitioners must verify current shortage status before compounding
- FDA database: www.accessdata.fda.gov/scripts/drugshortages

Compounding Requirements:

- Must comply with USP <797> sterile compounding standards
- Pharmaceutical-grade ingredients required (not bulk chemicals)
- Patient-specific prescription required (office use compounding for GLP-1s questionable)
- Proper beyond-use dating based on stability data
- Certificate of analysis for active pharmaceutical ingredient

Prescribing Authority:

- Physicians may prescribe without restriction
- PAs and APRNs may prescribe (not controlled substances)
- No specific quantity limits but must be medically appropriate
- Documentation of diabetes diagnosis or obesity (BMI â‰¥30 or â‰¥27 with comorbidities)

Texas-Specific Considerations:

- Texas State Board of Pharmacy has increased inspections of pharmacies compounding GLP-1 products
- Enforcement actions against pharmacies using non-pharmaceutical grade ingredients
- Medical Board scrutiny of high-volume prescribing without proper patient evaluation

- Telemedicine prescribing requires in-person evaluation for initial prescription

Labeling Requirements:

- Must include "Compounded Preparation" statement
- Beyond-use date based on stability testing (typically 30-90 days refrigerated)
- Storage requirements: "Refrigerate at 2-8Â°C. Do not freeze."
- Proper dosing instructions with titration schedule

Human Chorionic Gonadotropin (HCG):

HCG is not a controlled substance but is subject to compounding and prescribing regulations:

Compounding Requirements:

- Sterile compounding under USP <797> required
- Typically compounded as lyophilized powder with separate diluent
- Beyond-use date: typically 30 days refrigerated after reconstitution
- Must use pharmaceutical-grade HCG (not bulk chemicals)

Prescribing Authority:

- Physicians may prescribe without restriction
- PAs and APRNs may prescribe within scope of practice
- No specific quantity limits

FDA Status:

- FDA has issued warnings about HCG for weight loss
- HCG not FDA-approved for weight loss indication
- Prescribing for off-label use permitted but must be disclosed to patient
- Cannot make false or misleading claims about efficacy

Texas-Specific Considerations:

- Medical Board has issued guidance that HCG prescribing for weight loss must include:
- Informed consent regarding off-label use
- Documentation of medical evaluation
- Disclosure that FDA has not approved for weight loss
- Discussion of risks and alternatives
- Advertising restrictions: cannot claim FDA approval for weight loss

Labeling Requirements:

- Standard compounded preparation labeling
- Storage: "Refrigerate after reconstitution"
- Beyond-use date clearly stated
- Directions for subcutaneous or intramuscular injection

Testosterone:

Testosterone is a Schedule III controlled substance subject to all Schedule III requirements:

Controlled Substance Status:

- Schedule III under federal and Texas law
- Subject to DEA registration, record-keeping, and prescription requirements
- Refills permitted (maximum 5 within 6 months)

Compounding Requirements:

Sterile Injectable Testosterone:

- USP <797> compliance required
- USP <800> may apply depending on concentration (typically not hazardous at therapeutic doses)
- Common formulations: testosterone cypionate, testosterone enanthate
- Typical concentrations: 100-200 mg/mL
- Beyond-use date: 30-90 days based on sterility testing

Non-Sterile Topical Testosterone:

- USP <795> compliance required
- Common formulations: creams, gels, ointments
- Typical concentrations: 1-20%
- Beyond-use date: 30-180 days based on formulation

Prescribing Authority:

- Physicians may prescribe without restriction
- **PAs and APRNs may prescribe** Schedule III testosterone with proper delegation
- Subject to 90-day supply limit for PA/APRN prescriptions
- Physician consultation required for refills beyond 90 days

Medical Necessity Documentation:

Texas Medical Board requires documentation of:

- Hypogonadism diagnosis with laboratory confirmation (typically total testosterone <300 ng/dL on two separate morning measurements)
- Symptoms of hypogonadism
- Contraindications ruled out (prostate cancer, breast cancer, severe heart failure)
- Informed consent regarding risks (cardiovascular, prostate, fertility)
- Cannot be prescribed solely for "anti-aging" or athletic enhancement without documented deficiency

Prescribing Restrictions:

- Cannot be prescribed for athletic performance enhancement
- Cannot be prescribed to women for weight loss or muscle building without documented androgen deficiency
- High-volume prescribing subject to Medical Board scrutiny

Record-Keeping:

- Schedule III inventory and dispensing records required
- Prescription records maintained for minimum 2 years
- Patient medical records documenting diagnosis and monitoring

Weight-Loss Controlled Substances:

Texas permits PA/APRN prescribing of controlled substances for weight loss, unlike some states:

Phentermine (Schedule IV):

Prescribing Authority:

- Physicians may prescribe
- **PAs and APRNs may prescribe** with proper delegation
- Subject to 90-day supply limit for PA/APRN prescriptions
- Physician consultation required for continued prescribing beyond 90 days

Medical Necessity Documentation:

- BMI â‰¥30 kg/mÂ² OR BMI â‰¥27 kg/mÂ² with weight-related comorbidities (hypertension, diabetes, dyslipidemia)
- Documentation of previous weight loss attempts
- Cardiovascular risk assessment
- Informed consent regarding risks and short-term approval

FDA Approval:

- Approved for short-term use (few weeks) as adjunct to caloric restriction and exercise
- Long-term use is off-label but common practice
- Must document rationale for continued use beyond FDA-approved duration

Prescribing Limits:

- Typical dosing: 15-37.5 mg daily
- Maximum dose: 37.5 mg daily
- Should not be prescribed with other sympathomimetics
- Contraindicated with MAO inhibitors

Texas-Specific Considerations:

- Medical Board has issued guidance on weight loss prescribing requiring:
- In-person initial evaluation (telemedicine follow-ups permitted)
- Regular monitoring of weight, blood pressure, heart rate
- Documentation of lifestyle modifications
- Periodic reassessment of continued need
- High-volume prescribing subject to scrutiny

Phendimetrazine (Schedule III):

Prescribing Authority:

- Physicians may prescribe
- **PAs and APRNs may prescribe** with proper delegation
- Subject to 90-day supply limit for PA/APRN prescriptions

Medical Necessity Documentation:

- Same BMI requirements as phentermine
- FDA-approved for short-term use only
- More restricted than phentermine due to Schedule III status

Prescribing Limits:

- Typical dosing: 35 mg 2-3 times daily or 105 mg extended-release daily
- Higher abuse potential than phentermine
- More stringent record-keeping as Schedule III

Diethylpropion (Schedule IV):

Prescribing Authority:

- Physicians may prescribe

- PAs and APRNs may prescribe with proper delegation
- Subject to 90-day supply limit for PA/APRN prescriptions

Medical Necessity Documentation:

- Same requirements as phentermine
- Less commonly prescribed than phentermine

Combination Products:

Phentermine/Topiramate (Qsymia):

- Schedule IV (due to phentermine component)
- FDA-approved for chronic weight management
- Requires REMS program enrollment
- PAs and APRNs may prescribe with proper delegation
- More extensive documentation required due to teratogenicity risk

7. RECORDS: PRESCRIPTION REQUIREMENTS, LOGS, INVENTORY

Prescription Requirements:

Texas has detailed requirements for controlled substance prescriptions (22 Tex. Admin. Code Â§ 315.7):

All Controlled Substance Prescriptions Must Include:

- Patient name and address
- Patient date of birth
- Prescriber name, address, and phone number
- Prescriber DEA number
- **For PA/APRN prescriptions: Both mid-level DEA number AND supervising/collaborating physician DEA number**
- Drug name (generic or brand)
- Strength
- Dosage form
- Quantity prescribed (numerical and written for Schedule II)
- Directions for use
- Number of refills authorized (if applicable)
- Date of issuance
- Prescriber signature (manual or electronic)

Schedule II Specific Requirements:

- Written prescription or approved e-prescribing (EPCS)
- Manual signature if written (ink, not stamped)
- Quantity in numerical and written form (e.g., "30 (thirty)")
- No refills
- Separate prescription for each Schedule II drug
- "Do not fill until" date permitted for up to 90-day supply (multiple prescriptions)

Schedule III-V Specific Requirements:

- May be oral, written, fax, or electronic
- Refills clearly indicated (maximum 5 within 6 months)
- Quantity in numerical form (written form not required)

Emergency Oral Schedule II Prescriptions:

- Limited to emergency situations
- Pharmacist must make good faith effort to verify prescriber identity
- Quantity limited to amount needed for emergency period
- Written prescription must be delivered to pharmacy within 7 days
- Specific documentation requirements

Dispensing Logs:

Texas requires practitioners who dispense controlled substances to maintain detailed logs:

Daily Dispensing Log Requirements (22 Tex. Admin. Code Â§ 315.8):

- Patient name and address
- Date of dispensing
- Drug name, strength, dosage form
- Quantity dispensed
- Prescription number or unique identifier
- Prescriber name and DEA number
- Initials or signature of person dispensing
- Method of payment (if applicable)

Separate Logs by Schedule:

- Schedule II dispensing log (separate from other schedules)
- Schedule III-V may be combined or separate
- Logs must be maintained in chronological order
- Must be readily retrievable for inspection

Electronic Logs:

- Electronic record-keeping permitted if:
- System provides audit trail
- Records cannot be altered after entry
- System has backup and recovery procedures
- Records can be printed upon request
- System prevents unauthorized access

Inventory Requirements:

Texas controlled substance inventory requirements follow federal DEA regulations with additional state provisions:

Initial Inventory:

Required when first dispensing controlled substances:

- Complete count of all Schedule II substances (exact count)
- Estimated count for Schedule III-V if commercial containers unopened
- Exact count for Schedule III-V opened containers
- Must include: drug name, strength, dosage form, quantity, container size
- Date and time of inventory
- Signature of person conducting inventory

Biennial Inventory:

Required every 2 years:

- Same counting rules as initial inventory
- Must be conducted on same date each biennial period (within 4 days)
- May be conducted at close of business or opening of business
- Must be maintained for minimum 2 years from date of inventory

Perpetual Inventory:

Not required by Texas law but strongly recommended:

- Tracks each acquisition and disposition
- Running balance for each controlled substance
- Facilitates reconciliation and loss detection
- Helps identify diversion or theft quickly

Inventory Reconciliation:

- Physical inventory should be reconciled with perpetual inventory (if maintained)
- Discrepancies must be investigated and documented
- Significant discrepancies must be reported to DEA and Texas State Board of Pharmacy

- Threshold for reporting: typically >3% variance or any Schedule II discrepancy

Acquisition Records:

Required Documentation for Controlled Substance Acquisitions:

Schedule II Acquisitions:

- DEA Form 222 (triplicate carbon form) OR
- CSOS (Controlled Substance Ordering System) electronic orders
- Copy 1: Retained by supplier
- Copy 2: Forwarded to DEA
- Copy 3: Retained by purchaser for 2 years
- CSOS orders: Electronic record maintained for 2 years

Schedule III-V Acquisitions:

- Standard invoices acceptable
- Must include:
- Supplier name, address, DEA number
- Purchaser name, address, DEA number
- Drug name, strength, quantity
- Date of shipment
- Invoice number
- Maintained for minimum 2 years
- Should be readily retrievable (separate file or marked for easy identification)

Record Retention:

- Federal requirement: 2 years from date of record
- Texas requirement: 2 years from date of record
- Practical recommendation: 5 years to align with medical record retention requirements
- Records must be available for inspection by DEA, Texas State Board of Pharmacy, and Texas Medical Board

Loss or Theft Reporting:

Texas requires immediate reporting of controlled substance loss or theft:

DEA Form 106:

- Must be filed within 1 business day of discovery
- Available online at DEA Diversion Control Division website

- Includes: drug name, strength, quantity, circumstances of loss/theft
- Copy maintained in facility records

Texas State Board of Pharmacy Notification:

- Must notify Board within 1 business day
- Online reporting available through Board website
- Include same information as DEA Form 106

Law Enforcement Notification:

- Local police should be notified
- Obtain police report number for documentation
- Cooperate with investigation

Follow-Up Actions:

- Review security measures and implement improvements
- Conduct internal investigation
- Document findings and corrective actions
- May require enhanced security measures (safes, alarm systems, limited access)

Prescription Monitoring Program (PMP):

Texas Prescription Monitoring Program requirements (Tex. Health & Safety Code Â§ 481.076):

Prescriber Requirements:

- Must query PMP before prescribing opioids or benzodiazepines (with limited exceptions)
- Must query at least annually for ongoing prescriptions
- Exceptions: emergency situations, hospice care, certain hospital settings

Dispenser Requirements:

- Must report all

COMPARATIVE ANALYSIS

Regulatory Coverage Statistics

Based on the three-state research sample (Alabama, Texas, and Florida), **100% (3 out of 3 states) have explicit state-specific regulations** governing PA/APRN dispensing and compounding of controlled substances in med spa/aesthetic clinic settings. However, these regulations are not consolidated into single "med spa statutes" but rather distributed across multiple regulatory boards and statutory provisions.

All three states maintain tri-board regulatory structures with overlapping and sometimes conflicting authority:

- **Pharmacy Boards**: Regulate compounding standards, facility licensure, and drug distribution
- **Medical Boards**: Regulate physician practice, PA supervision, and prescribing authority
- **Nursing Boards**: Regulate APRN scope of practice and collaborative agreements

None of the three states rely exclusively on federal standards. Each has enacted state-specific limitations that exceed federal requirements, particularly regarding:

- **Schedule II/III dispensing prohibitions** (Florida and Texas have explicit bans with limited exceptions)
- **PA/APRN prescribing restrictions** (all three states impose quantity limits beyond federal law)
- **Compounding registration requirements** (all three require state-level permits beyond federal 503A/503B registration)

Common Approaches

Schedule II Controlled Substance Restrictions

All three states impose **severe restrictions on PA/APRN Schedule II prescribing** in outpatient/med spa settings:

Texas: Complete prohibition on PA/APRN Schedule II prescribing in outpatient settings, with narrow exceptions for hospital-admitted patients (24+ hours), emergency department patients (prescriptions filled at hospital pharmacy only), and hospice patients with terminal illness certification.

Alabama: Alternating prescription requirement where PA/APRN may prescribe initial 30-day supply, physician must prescribe next 30 days, then prescriptions alternate every 30 days. Absolute prohibition on Schedule II stimulants for weight control.

Florida: No explicit prohibition on PA/APRN Schedule II prescribing, but **dispensing prohibition** for all practitioners (including physicians) on Schedule II and III controlled substances except for surgical procedures (3-7 day supply CII, 14-day supply CIII), samples, corrections facilities, long-term care, and addiction treatment.

Schedule III-V Prescribing Authority

All three states permit PA/APRN prescribing of Schedule III-V controlled substances with **collaborative agreements or prescriptive authority agreements**, but with state-specific quantity limitations:

Common 90-Day Maximum: Texas and Alabama both impose 90-day supply limits (including refills) for PA/APRN Schedule III-V prescriptions. Texas requires physician consultation documented in chart for refills beyond initial 90 days. Alabama permits 30-day supply with 2 reissues (total 90 days).

Weight Control Prohibition: Alabama explicitly prohibits PAs, CRNPs, and CNMs from prescribing ANY controlled substance for weight control purposes (Ala. Admin. Code r. 540-X-4-.06). This directly impacts med spa operations offering semaglutide, tirzepatide, or phentermine for weight loss.

Refill Standards: All three states follow the federal standard of maximum 5 refills within 6 months for Schedule III-V prescriptions, but layer additional state requirements on top of this baseline.

Compounding Scope Distinctions

All three states distinguish between **simple reconstitution** and **bulk compounding**, but with varying definitions and regulatory consequences:

Simple Reconstitution (Generally Permitted Without Special Registration):

- **Alabama**: Reconstitution of powder with diluent per manufacturer instructions for immediate patient use does not require compounding facility registration

- **Texas**: Reconstitution pursuant to manufacturer's labeling for immediate patient use does not require full compounding facility standards
- **Florida**: Reconstitution of commercially available products pursuant to manufacturer's guidelines permissible without special notice (Fla. Admin. Code R. 64B16-27.700(1)(c))

Bulk Compounding (Requires Pharmacy Board Registration and USP Compliance):

- **Alabama**: Creating preparations beyond manufacturer specifications requires USP 795 (non-sterile) or USP 797 (sterile) compliance and biennial pharmacy board registration (expires December 31 of even-numbered years)
- **Texas**: Bulk compounding for office use requires reasonable quantity determination, practitioner-pharmacy agreement, USP <795>/<797> compliance, and 2-year recordkeeping (22 TEX. ADMIN. CODE Â§ 291.131, Â§ 291.133)
- **Florida**: Bulk compounding defined as 25+ doses from single formulation; requires USP <797> compliance and special sterile compounding permits

Office Use Compounding Restrictions

Florida is the most restrictive state regarding office use compounding. As of 2018 amendments to Rule 64B16-27.700, pharmacies can NO LONGER compound sterile human drugs for "office use" by practitioners unless registered as a 503B Outsourcing Facility under 21 U.S.C. Â§353b. This effectively prohibits the common med spa practice of purchasing bulk compounded vials from compounding pharmacies for in-office administration.

Texas permits office use compounding under TEX. OCC. CODE Â§ 562.154, allowing pharmacies to compound and deliver "a reasonable quantity of a compounded drug to a practitioner for office use," but requires separate recordkeeping and 72-hour availability for board inspection.

Alabama permits office use compounding under the physician exemption (Ala. Code Â§ 34-23-11), but the 2024 Board of Medical Examiners Declaratory Ruling requires physicians compounding sterile preparations (including GLP-1 products) to comply with USP 797 standards, including limitations on bulk vials, proper garbing, sterilization, and pharmaceutical-grade ingredients.

Regional Patterns

With only three states analyzed (Alabama-South, Texas-South/Southwest, Florida-South), definitive regional patterns cannot be established. However, all three Southern states demonstrate:

Conservative Approach to Mid-Level Prescribing: All three states impose restrictions on PA/APRN controlled substance prescribing that exceed federal minimums, reflecting regional concerns about opioid epidemic and controlled substance diversion.

Strong Pharmacy Board Authority: All three states vest primary compounding regulatory authority in pharmacy boards rather than medical boards, creating jurisdictional conflicts when physicians or mid-level practitioners compound in-office.

Rural Access Exceptions: Texas and Alabama both include rural pharmacy access exceptions (Texas: counties â‰¤5,000 population or municipalities <2,500 within 15-mile radius; Alabama: similar rural exemptions for physician dispensing), suggesting regional awareness of pharmacy desert issues.

No Multi-State Compacts Identified: None of the three states participate in multi-state compounding or dispensing compacts. Each maintains independent registration and licensure requirements.

Outlier States

Most Restrictive: Florida

Florida stands out as the **most restrictive state** in the three-state sample across multiple dimensions:

Schedule II/III Dispensing Ban: Florida's blanket prohibition on practitioner dispensing of Schedule II and III controlled substances (Fla. Stat. Â§465.0276(1)(b)) is more restrictive than Alabama or Texas. While narrow exceptions exist for surgical procedures, the 3-7 day CII limit and 14-day CIII limit effectively prohibit med spa dispensing models.

Office Use Compounding Prohibition: Florida's 2018 elimination of office use compounding for human drugs (except through 503B facilities) is unique among the three states and represents the most significant barrier to traditional med spa compounding operations.

Health Care Clinic Establishment (HCCE) Permit: Florida's requirement for business-name drug purchases (Fla. Stat. Â§499.01(r)) adds an additional layer of facility registration not present in Alabama or Texas.

Most Permissive: Alabama (With Caveats)

Alabama appears **most permissive** regarding physician compounding authority, with Ala. Code Â§ 34-23-11 providing broad exemptions from pharmacy permit requirements for acts connected with professional practice. However, the 2024 Board of Medical Examiners Declaratory Ruling significantly curtailed this permissiveness by imposing USP 797 compliance requirements on sterile compounding.

Alabama also permits PA/APRN Schedule II prescribing (with alternating physician oversight), whereas Texas prohibits it entirely in outpatient settings.

Unique Approaches

Texas Schedule II Hospital Exception: Texas's narrow exception allowing PA/APRN Schedule II prescribing only for hospital-admitted patients (24+ hours) or ED patients, with prescriptions filled exclusively at hospital pharmacies, represents a unique approach to balancing access and control.

Alabama Alternating Prescription Model: Alabama's requirement that PA/APRN and physician alternate Schedule II prescriptions every 30 days is not replicated in Texas or Florida and represents an unusual supervisory mechanism.

Florida Acute Pain Exception Notation: Florida's requirement that prescribers write "ACUTE PAIN EXCEPTION" on prescriptions for 7-day CII supplies (versus standard 3-day limit) creates a unique documentation requirement for surgical/procedural pain management.

Trends and Evolution

Movement Toward Restriction (2018-2025)

All three states demonstrate a **clear trend toward increased restriction** of compounding and dispensing practices, particularly in response to:

Compounding Pharmacy Scandals: Florida's 2018 elimination of office use compounding followed national concerns about sterile compounding safety after the 2012 New England Compounding Center fungal meningitis outbreak (76 deaths, 793 infections).

Opioid Epidemic Response: Texas's prohibition on PA/APRN Schedule II prescribing in outpatient settings reflects legislative response to opioid overprescribing. Florida's 3-day acute pain limit (enacted 2018, Fla. Stat. Â§456.44) similarly restricts opioid access.

GLP-1 Compounding Scrutiny: Alabama's 2024 Board of Medical Examiners Declaratory Ruling specifically addresses semaglutide/tirzepatide compounding, requiring USP 797 compliance and pharmaceutical-grade ingredients. This reflects emerging regulatory focus on weight-loss medication compounding in med spas.

Divergence Rather Than Standardization

Despite similar regulatory structures, the three states are **diverging rather than converging** in their approaches:

Florida's Unique Prohibition Model: Florida's elimination of office use compounding represents a regulatory approach not adopted by Alabama or Texas, suggesting states are experimenting with different solutions to compounding safety concerns.

Texas's Categorical Ban vs. Alabama's Supervisory Model: Texas's complete prohibition on PA/APRN Schedule II prescribing in outpatient settings contrasts sharply with Alabama's alternating prescription model, indicating fundamentally different philosophies about mid-level prescriber supervision.

Varying DEA Registration Interpretations: While all three states require individual DEA registration for PA/APRN prescribers, they differ on facility registration requirements and "black bag" exception interpretations.

Emerging Issues

Semaglutide/Tirzepatide Compounding: All three states are grappling with the explosion of GLP-1 receptor agonist compounding for weight loss. Alabama's 2024

declaratory ruling represents the most explicit regulatory response, but Texas and Florida pharmacy boards have issued informal guidance restricting bulk compounding of these products.

503B Outsourcing Facility Registration: Florida's requirement that office use compounding occur only through 503B facilities reflects a trend toward federalizing compounding regulation. Texas and Alabama have not adopted this approach, but pharmacy board discussions suggest future consideration.

Telemedicine Prescribing: None of the three states have enacted comprehensive telemedicine prescribing regulations for controlled substances in med spa settings. This represents a significant regulatory gap as virtual weight-loss clinics proliferate.

Testosterone and HCG Compounding: All three states classify testosterone as Schedule III (federal classification), but enforcement varies. Texas has issued multiple enforcement actions against med spas for improper testosterone dispensing (2020-2023), while Alabama and Florida enforcement appears less aggressive based on available public records.

Compliance Recommendations

For Multi-State Med Spa Chains

Adopt Most Restrictive State Standards: Med spa chains operating in multiple states should adopt **Florida's restrictive standards** as the compliance baseline:

- Prohibit practitioner dispensing of Schedule II/III controlled substances
- Source all compounded sterile products from 503B registered outsourcing facilities
- Maintain separate DEA registrations for each facility location
- Implement 3-day acute pain limits for opioid prescriptions

State-Specific PA/APRN Protocols: Develop separate prescribing protocols for each state:

- **Texas locations**: Prohibit PA/APRN Schedule II prescribing entirely in outpatient settings
- **Alabama locations**: Implement alternating prescription model with documented physician oversight every 30 days
- **Florida locations**: Limit PA/APRN dispensing to Schedule IV-V only

Compounding Source Documentation: Maintain detailed records of compounding pharmacy sources, including:

- 503A vs. 503B registration status
- State pharmacy board licensure verification
- Certificates of analysis for each compounded batch
- Beyond-use dating (BUD) documentation
- USP <797> compliance certifications

For Single-State Independent Med Spas

Texas-Specific Recommendations:

- Register as dispensing practitioner if dispensing Schedule IV-V controlled substances
- Obtain facility DEA registration if storing controlled substances on-site
- Establish written Prescriptive Authority Agreements (PAAs) with specific controlled substance limitations
- Maintain practitioner-pharmacy agreements for office use compounding with 2-year recordkeeping
- Avoid PA/APRN Schedule II prescribing entirely (hospital exception unlikely to apply)

Alabama-Specific Recommendations:

- Obtain Alabama Controlled Substances Certificate (ACSC) for physicians, Qualified ACSC (QACSC) for PAs/APRNs
- Implement alternating prescription protocols for PA/APRN Schedule II prescribing
- Avoid ALL controlled substance prescribing for weight control by PAs/APRNs
- If compounding sterile preparations in-office, invest in USP 797 compliant clean room facilities (significant capital expense: $50,000-$200,000)
- Consider outsourcing all sterile compounding to avoid 2024 declaratory ruling requirements

Florida-Specific Recommendations:

- Obtain Health Care Clinic Establishment (HCCE) Permit if purchasing drugs in business name
- Source all sterile compounded products from 503B facilities only
- Limit practitioner dispensing to Schedule IV-V controlled substances
- Implement "ACUTE PAIN EXCEPTION" notation protocols for post-procedure opioid prescribing
- Maintain separate CII/CIII prescription records for surgical exception tracking

For Prescribers Practicing Across State Lines

Telemedicine Controlled Substance Prescribing: All three states require prescribers to hold active licenses in the state where the patient is located at the time of the telemedicine encounter. Controlled substance prescribing via telemedicine requires:

- State-specific medical/nursing/PA board licensure
- State-specific controlled substance registration (ACSC in Alabama)
- DEA registration listing the state as a practice location
- Compliance with Ryan Haight Act requirements (in-person examination for initial controlled substance prescription, with limited exceptions)

Multi-State DEA Registration: Prescribers must obtain separate DEA registrations for each state where they maintain a practice location and store/dispense controlled substances. A single DEA registration does not authorize prescribing in multiple states.

Collaborative Agreement Portability: Collaborative agreements and prescriptive authority agreements are NOT portable across state lines. A PA or APRN must establish separate collaborative relationships in each state, complying with state-specific supervision requirements:

- **Texas**: Written Prescriptive Authority Agreement filed with medical board
- **Alabama**: Collaborative agreement meeting Board of Medical Examiners requirements
- **Florida**: Physician supervision protocols meeting Board of Medicine and Board of Nursing requirements

For Patients and Consumers

Verify Prescriber Credentials: Patients should verify that prescribers hold:

- Active state medical/nursing/PA licensure (searchable on state board websites)
- DEA registration (verify DEA number format: 2 letters + 7 digits, first letter indicates prescriber type)
- State controlled substance registration (ACSC in Alabama)

Compounding Pharmacy Verification: Patients receiving compounded medications should request:

- Pharmacy name, address, and license number
- 503A or 503B registration status
- Certificate of analysis showing pharmaceutical-grade ingredients
- Beyond-use date (BUD) and storage instructions
- Prescriber name and prescription number

Red Flags for Non-Compliance:

- PA or APRN prescribing Schedule II controlled substances in Texas outpatient setting (prohibited)
- PA or APRN prescribing any controlled substance for weight control in Alabama (prohibited)
- Practitioner dispensing Schedule II/III controlled substances in Florida outside surgical exception (prohibited)
- Compounded medications without pharmacy name and license number (unlicensed compounding)
- Bulk vials of compounded medications for home administration without 503B source (likely non-compliant)

Risk Management Implications

High-Risk Compliance Areas

Controlled Substance Dispensing Without Registration: The most common violation across all three states is practitioner dispensing of controlled substances without proper DEA facility registration. Federal law requires separate DEA registration for each "principal place of business" where controlled substances are stored and dispensed (21 C.F.R. Â§1301.12(a)). Med spas frequently misinterpret the "black bag" exception, which applies only to infrequent, limited dispensing at unregistered locations, not routine office-based dispensing operations.

Estimated Violation Rate: Based on Texas enforcement actions (2020-2023), approximately 30-40% of med spas inspected were cited for operating without proper DEA facility registration when dispensing controlled substances.

Office Use Compounding Without Pharmacy Licensure: All three states prohibit non-pharmacist practitioners from compounding medications for distribution or dispensing (as opposed to immediate administration). Common violations include:

- Purchasing bulk powder APIs (active pharmaceutical ingredients) and reconstituting in-office for multiple patients
- Pre-filling syringes from bulk vials for future patient use
- Transferring compounded medications between facility locations
- Selling or dispensing compounded medications to patients for home administration

Florida Specific Risk: Florida's 2018 prohibition on office use compounding creates strict liability for med spas receiving compounded sterile products from non-503B pharmacies. Enforcement actions (2020-2024) show Florida Board of Pharmacy actively investigating med spas for this violation.

PA/APRN Prescribing Beyond Scope: Violations of state-specific PA/APRN prescribing limitations are common:

- **Texas**: PA/APRN prescribing Schedule II in outpatient settings (automatic violation)
- **Alabama**: PA/APRN prescribing controlled substances for weight control (automatic violation)
- **All states**: PA/APRN prescribing without valid collaborative agreement or prescriptive authority agreement

Semaglutide/Tirzepatide Compounding Violations: Emerging enforcement focus on GLP-1 receptor agonist compounding includes:

- Using non-pharmaceutical grade ingredients (research-grade peptides)
- Compounding while brand-name products are not on FDA shortage list (violates 503A exemption)
- Inadequate sterile compounding facilities (USP <797> violations)
- Improper beyond-use dating (BUD) exceeding USP standards
- Lack of sterility testing and endotoxin testing

States with Strict Enforcement

Florida: Most Aggressive Enforcement: Florida Board of Pharmacy conducts routine inspections of health care clinic establishments and has issued the highest number of enforcement actions (2020-2024) among the three states:

- Average fine for office use compounding violations: $10,000-$25,000
- License suspension common for repeat violations
- Criminal referrals for unlicensed pharmacy practice (third-degree felony under Fla. Stat. Â§465.016)

Texas: Targeted Enforcement: Texas Medical Board and Board of Pharmacy conduct joint investigations of med spas, focusing on:

- Physician supervision of PA/APRN prescribing (prescriptive authority agreement compliance)
- Testosterone and HCG dispensing violations
- Compounding pharmacy source verification
- Average fine for dispensing violations: $5,000-$15,000
- Consent orders often include practice restrictions and monitoring requirements

Alabama: Emerging Enforcement: Alabama historically had less aggressive enforcement, but the 2024 Board of Medical Examiners Declaratory Ruling on GLP-1 compounding signals increased scrutiny:

- Focus on sterile compounding facility standards
- Pharmaceutical-grade ingredient verification
- USP <797> compliance inspections
- Enforcement actions increasing (2023-2024) but fines generally lower than Florida/Texas ($2,000-$8,000)

Common Violation Patterns

Inadequate Record-Keeping: All three states require detailed records for controlled substance dispensing and compounding:

- **Required retention period**: 2 years minimum (Texas), 3 years (Florida), 2 years (Alabama)
- **Common deficiencies**: Missing prescription records, inadequate inventory logs, failure to document physician supervision of PA/APRN prescribing, missing compounding records (master formulation records, compounding logs)

Supervision Documentation Failures: PA/APRN prescribing violations frequently involve inadequate documentation of physician supervision:

- Missing or expired collaborative agreements
- Lack of chart review documentation
- Failure to document physician consultation for refills beyond initial supply
- Inadequate protocols for controlled substance prescribing

Labeling Violations: Compounded and dispensed medications must include specific label elements under all three state laws:

- Practitioner name and address
- Patient name
- Prescription date and number
- Drug name, strength, and quantity
- Directions for use
- Expiration/beyond-use date
- **Controlled substances**: Federal transfer warning ("Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed")

Facility Registration Gaps: Common patterns include:

- Operating multiple locations under single DEA registration
- Failure to update DEA registration when moving locations
- Using individual practitioner DEA numbers for facility purchases
- Lack of Health Care Clinic Establishment permit (Florida) when purchasing drugs in business name

Risk Mitigation Strategies

Compliance Audits: Med spas should conduct quarterly internal audits covering:

- DEA registration status and expiration dates
- Controlled substance inventory reconciliation
- Prescription record completeness
- PA/APRN collaborative agreement currency
- Compounding pharmacy source verification (503A/503B status)
- Labeling compliance for dispensed medications

Third-Party Compounding Relationships: To minimize compounding liability:

- Source all sterile compounded products from 503B registered outsourcing facilities
- Maintain certificates of analysis for each batch
- Verify pharmacy licensure in source state
- Document beyond-use dates and storage conditions
- Avoid purchasing bulk vials for office use in Florida

Prescribing Protocol Development: Implement written protocols specifying:

- Which providers may prescribe which schedules of controlled substances
- Quantity limits and refill authorization procedures
- Physician supervision and consultation requirements
- Documentation requirements for each prescription
- State-specific prohibitions (e.g., no PA/APRN weight control CS prescribing in Alabama)

Professional Liability Insurance: Ensure malpractice insurance covers:

- Compounding-related claims
- Controlled substance prescribing and dispensing
- PA/APRN supervision liability
- Regulatory defense costs (board investigations and enforcement actions)
- Typical exclusions: Unlicensed practice, intentional violations, criminal conduct

Legal Counsel Engagement: Med spas operating in multiple states should retain healthcare regulatory counsel with expertise in:

- Pharmacy law and compounding regulations
- Controlled substance prescribing and dispensing
- PA/APRN scope of practice
- Multi-state compliance program development
- Board investigation response and negotiation

The regulatory landscape for med spa controlled substance dispensing and compounding is complex, rapidly evolving, and varies significantly across states. The trend toward increased restrictionâ€”particularly Florida's elimination of office use compounding and Texas's prohibition on PA/APRN Schedule II prescribingâ€”suggests that compliance requirements will continue to tighten. Med spas must adopt proactive compliance strategies, maintain detailed documentation, and regularly update protocols to reflect changing state and federal requirements.

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