Corporate Policies & Procedures Manual

DERMALYNX DISTRIBUTION, LLC

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Classification: Company Confidential

Approved by: Compliance Officer, Dermalynx Distribution, LLC

This document contains the complete corporate policies and procedures framework for Dermalynx Distribution, LLC. It is intended for all personnel, contractors, and authorized representatives.

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SECTION 1

Company Overview & Mission

Dermalynx Distribution, LLC ("Dermalynx" or "the Company") is a Wyoming limited liability company established in 2026 as an FDA-registered distributor of human cellular and tissue-based products (HCT/Ps). The Company operates as a compliant intermediary between FDA-registered tissue manufacturers and licensed healthcare facilities, government agencies, and authorized end users.

Mission Statement. To establish the industry standard for compliant cellular tissue product distribution through transparent operations, rigorous regulatory adherence, and unwavering commitment to patient safety.

Core Values.

- Regulatory compliance as a non-negotiable operational requirement
- Transparency in all commercial relationships and pricing
- Patient safety through complete chain-of-custody documentation
- Ethical conduct in every transaction, referral, and communication
- Continuous improvement through monitoring, auditing, and training

Scope of Operations. Dermalynx distributes FDA-registered HCT/P products including amniotic membrane, acellular dermis, skin substitutes, placental tissues, injectable amniotics, and umbilical cord-derived products. The Company does not manufacture, process, or perform any steps in tissue recovery or processing.

SECTION 2

Compliance Program Structure

Dermalynx maintains a comprehensive compliance program modeled on the seven elements of an effective compliance program as recommended by the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services.

2.1 Seven Elements of Compliance

1. Written Policies and Procedures. This manual and all referenced sub-policies constitute the Company's written standards of conduct and compliance procedures.

2. Compliance Officer and Committee. A designated Compliance Officer has the authority, resources, and organizational independence to implement, monitor, and enforce the compliance program.

3. Training and Education. All personnel complete initial and annual compliance training covering AKS, FDA regulations, cGTP, and Company-specific policies.

4. Effective Lines of Communication. A confidential compliance hotline and direct reporting channels are available to all personnel for reporting concerns without fear of retaliation.

5. Internal Monitoring and Auditing. Monthly compliance dashboards, quarterly internal audits, and annual comprehensive program reviews ensure ongoing effectiveness.

6. Enforcement Through Disciplinary Guidelines. Violations of compliance policies result in consistent disciplinary action, up to and including termination and regulatory referral.

7. Prompt Response to Detected Offenses. Identified compliance issues trigger immediate investigation, corrective action, and, where required, self-disclosure to appropriate authorities.

2.2 Compliance Officer Responsibilities

The Compliance Officer reports directly to the Company's principal(s) and is responsible for: overseeing day-to-day compliance operations; developing and revising policies; conducting risk assessments; managing OIG exclusion screening; coordinating training programs; receiving and investigating compliance reports; preparing compliance reports for management; and liaising with external regulatory bodies as needed.

SECTION 3

Anti-Kickback Statute (AKS) Compliance

The federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration to induce or reward the referral of items or services payable by a federal healthcare program.

3.1 Prohibited Conduct

- Offering or paying anything of value to healthcare providers to induce product purchases or referrals
- Volume-based or revenue-contingent compensation for sales representatives
- Providing free products, samples, or services as inducement for future orders
- Entertainment, gifts, or meals exceeding nominal value to current or prospective customers
- Consulting arrangements that are not at fair market value for legitimate, documented services
- Sham advisory boards or speaker programs designed to reward referral sources

3.2 Compliant Compensation Structures

All sales representatives are compensated using fixed-fee arrangements that are not contingent on the volume or value of products ordered. Compensation is set at fair market value, determined in advance, documented in written agreements, and reviewed annually. No bonuses, commissions, or incentives are tied to individual account purchasing volume.

3.3 Pricing Policy

Dermalynx maintains uniform, transparent pricing. Discounts are offered only through documented discount programs that comply with the AKS discount safe harbor (42 C.F.R. § 1001.952(h)). All discounts are properly reported to allow customers to accurately report costs to federal healthcare programs.

SECTION 4

FDA Regulatory Compliance (21 CFR Part 1271)

As an FDA-registered HCT/P establishment, Dermalynx complies with all applicable requirements under 21 CFR Part 1271, including establishment registration, product listing, adverse event reporting, and recordkeeping requirements.

4.1 Establishment Registration

Dermalynx maintains current FDA establishment registration and updates its registration annually or within 30 days of any material change in operations, as required by 21 CFR § 1271.21.

4.2 Product Listing

All distributed HCT/P products are listed with the FDA. The Company verifies that each manufacturer's products maintain current FDA listing before accepting inventory or fulfilling orders.

4.3 Adverse Event Reporting

Any adverse reaction or product complaint is documented and reported to the manufacturer within 24 hours. Reportable events are submitted to the FDA via MedWatch within the applicable timeframe. The Company maintains a log of all complaints and adverse events with resolution documentation.

4.4 Supplier Qualification

Dermalynx only distributes products from manufacturers who maintain current FDA registration, comply with donor eligibility requirements under 21 CFR § 1271.50, and operate under validated cGTP procedures. Manufacturer qualification is re-verified annually.

SECTION 5

Current Good Tissue Practice (cGTP)

Dermalynx adheres to current Good Tissue Practice (cGTP) requirements under 21 CFR Part 1271, Subpart D, as applicable to distribution operations.

5.1 Environmental Controls

All storage facilities maintain temperature controls appropriate for the products stored. Temperature monitoring is continuous (24/7) with automated alerts for excursions. Backup power systems are in place. Temperature logs are retained for the life of the product plus ten years.

5.2 Chain of Custody

Every product unit is tracked from receipt through final delivery at the lot level. Chain-of-custody documentation includes: manufacturer lot number, date of receipt, storage conditions, shipping method, delivery confirmation, and recipient facility identification.

5.3 Product Recalls

In the event of a manufacturer-initiated recall, Dermalynx can identify and locate all affected units within 24 hours. The Company maintains a recall notification system to alert all affected customers immediately upon notice of a recall.

SECTION 6

Product Handling, Storage & Distribution

6.1 Receiving Procedures

All incoming shipments are inspected upon receipt. Inspection includes verification of: product identity and lot number, package integrity, temperature indicator status, shipping documentation completeness, and expiration dates. Products that fail inspection are quarantined and the manufacturer is notified.

6.2 Storage Requirements

Products are stored according to manufacturer specifications. Ambient, refrigerated (2–8°C), and frozen (-20°C or below) storage areas are maintained with continuous monitoring. Access to storage areas is restricted to authorized personnel.

6.3 Shipping & Delivery

Products are shipped using validated packaging and shipping methods that maintain required temperature ranges throughout transit. Delivery confirmation is obtained for every shipment. Products are shipped only to verified, licensed healthcare facilities.

SECTION 7

Customer Due Diligence & Onboarding

Dermalynx conducts thorough due diligence on all customers before the first transaction and on an ongoing quarterly basis thereafter.

7.1 Pre-Onboarding Requirements

- Verification of active state medical/professional license
- Confirmation of facility licensing and accreditation
- OIG List of Excluded Individuals/Entities (LEIE) screening
- SAM.gov exclusion verification
- State Medicaid exclusion list screening
- Completion of Customer Compliance Certification form
- Verification of DEA registration (where applicable)

7.2 Ongoing Monitoring

All customers are rescreened monthly against OIG LEIE, SAM.gov, and applicable state exclusion lists. License status is reverified quarterly. Any adverse finding results in immediate suspension of the account pending investigation.

SECTION 8

Sales & Marketing Policies

8.1 Truthful and Non-Misleading Communications

All sales and marketing materials must be accurate, balanced, and consistent with FDA-cleared indications. No off-label promotion is permitted. All materials are reviewed by the Compliance Officer before use.

8.2 Interactions with Healthcare Professionals

All interactions with healthcare professionals must have a legitimate business purpose. Meals, if provided, must be modest, infrequent, and directly related to a substantive business discussion. No entertainment, recreational events, or gifts of any kind are permitted.

8.3 Prohibited Marketing Practices

- Providing clinical recommendations or medical advice
- Making comparative claims not supported by published evidence
- Disparaging competitor products with unsubstantiated claims
- Using patient testimonials without proper authorization
- Promising specific clinical outcomes

SECTION 9

Record Retention & Documentation

Dermalynx maintains comprehensive records in accordance with FDA requirements, applicable state laws, and industry best practices.

9.1 Retention Periods

Record Type	Retention Period
Product distribution records	10 years from distribution date
Temperature monitoring logs	Life of product + 10 years
Customer due diligence files	Duration of relationship + 7 years
Compliance training records	7 years from training date
Adverse event reports	10 years from report date
Financial and compensation records	7 years
Contracts and agreements	Duration + 7 years
Compliance investigation files	10 years from resolution

SECTION 10

Training & Education Requirements

10.1 Initial Training

All new personnel complete compliance training within 30 days of hire. Training covers: this Policies & Procedures Manual; Anti-Kickback Statute fundamentals; FDA HCT/P regulatory requirements; cGTP procedures; HIPAA privacy and security (where applicable); and the Company's reporting and escalation procedures.

10.2 Annual Refresher Training

All personnel complete annual refresher training. Content is updated to reflect regulatory changes, audit findings, and industry developments. Completion is tracked and documented.

10.3 Specialized Training

Personnel in roles with heightened compliance risk (sales, customer onboarding, product handling) receive additional role-specific training. The Compliance Officer determines specialized training requirements based on annual risk assessments.

SECTION 11

Reporting, Monitoring & Auditing

11.1 Compliance Reporting

All personnel have an obligation to report known or suspected compliance violations. Reports may be made to the Compliance Officer directly, via the confidential compliance hotline, or through email at compliance@dermalynx.co. Retaliation against good-faith reporters is strictly prohibited and is itself a terminable offense.

11.2 Monitoring Activities

- Monthly OIG/SAM exclusion screening of all personnel and customers
- Monthly compliance dashboard review (KPIs, open issues, training status)
- Quarterly customer due diligence re-verification
- Quarterly compensation arrangement review
- Annual comprehensive compliance program assessment

11.3 Internal Audits

Quarterly internal audits are conducted by the Compliance Officer or designee. Audit scope rotates to cover all major compliance areas within each calendar year. Findings are documented with corrective action plans and tracked to resolution.

SECTION 12

Disciplinary Actions & Enforcement

Violations of this manual or any Company compliance policy are subject to disciplinary action. Discipline is applied consistently regardless of the violator's position or tenure.

12.1 Disciplinary Spectrum

- Verbal warning with documented counseling
- Written warning with corrective action plan
- Suspension pending investigation
- Termination of employment or contract
- Referral to applicable regulatory or law enforcement authorities

12.2 Factors Considered

Severity and scope of the violation, whether the violation was intentional or negligent, whether the individual self-reported the violation, the individual's compliance history, and the potential harm to patients, customers, or the Company are all considered in determining appropriate discipline.

This manual is reviewed and updated annually or more frequently as required by regulatory changes. Questions regarding any policy should be directed to the Compliance Officer at compliance@dermalynx.co.