DERMALYNX DISTRIBUTION, LLC

CORPORATE POLICIES & PROCEDURES MANUAL

Cellular Tissue Product Distribution
Government & Commercial Healthcare Sector

Revision 1.0 | Effective Date: March 19, 2026

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SECTION 1 — INTRODUCTION AND COMPANY OVERVIEW

1.1 Company Background. Dermalynx Distribution, LLC ("Dermalynx" or the "Company") is a Wyoming limited liability company engaged in the wholesale distribution of cellular tissue products (CTPs), human cell, tissue, and cellular and tissue-based products (HCT/Ps), medical devices, and related supplies and equipment to licensed healthcare facilities, government agencies, and healthcare practitioners throughout the United States.

1.2 Mission Statement. Dermalynx Distribution is committed to advancing patient care outcomes through the reliable, compliant, and efficient distribution of life-enhancing cellular tissue products. We serve our customers — including federal government agencies and Veterans Affairs medical centers — with integrity, accountability, and clinical excellence.

1.3 Core Values. The Company operates according to the following core values:

- Integrity — We conduct all business with uncompromising honesty and transparency.
- Compliance — We adhere to all applicable federal and state laws, regulations, and contractual obligations.
- Quality — We maintain the highest standards of product handling, storage, and chain-of-custody documentation.
- Patient Safety — All decisions are made with patient safety as the paramount consideration.
- Accountability — Every employee, contractor, and agent is responsible for upholding these policies.

1.4 Scope. This Corporate Policies & Procedures Manual ("Manual") applies to all officers, managers, employees, contractors, sales agents, and other personnel acting on behalf of Dermalynx Distribution, LLC. Compliance with the policies set forth herein is a condition of employment or engagement with the Company.

SECTION 2 — REGULATORY COMPLIANCE POLICY

POLICY 2.0

Regulatory Compliance Policy

Rev. 1.0 | Effective: March 19, 2026 | Owner: Compliance & Quality Officer

2.1 Purpose

To ensure that Dermalynx Distribution, LLC maintains full compliance with all applicable federal and state laws, regulations, and standards governing the distribution of cellular tissue products, and to establish a framework for identifying, monitoring, and responding to regulatory requirements.

2.2 FDA Compliance — 21 CFR Part 1271 (HCT/Ps)

All cellular tissue products distributed by the Company are regulated as Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) under 21 CFR Part 1271. The Company shall:

- Maintain current registration as an HCT/P Establishment with the FDA Center for Biologics Evaluation and Research (CBER), with annual updates as required under 21 CFR § 1271.21.
- Distribute only HCT/Ps from FDA-registered and compliant tissue establishments with documented current Good Tissue Practice (cGTP) status.
- Maintain complete traceability records from donor to final disposition for a minimum of ten (10) years pursuant to 21 CFR § 1271.290.
- Verify that all distributed HCT/Ps are accompanied by appropriate labels and documentation including donor eligibility determination status, expiration date, and storage requirements.
- Implement a quarantine procedure for any product of uncertain regulatory status pending verification.
- Maintain a product recall/retrieval capability and cooperate fully with any FDA-initiated recall under 21 CFR Part 7.
- Not distribute any HCT/P that has been removed from the market, placed on FDA import alert, or is the subject of an active recall without explicit authorization from the Compliance Officer.

2.3 State Distributor Licensing

The Company shall obtain and maintain all required state wholesale drug/device distributor or tissue bank licenses in each state where distribution activities occur. The Compliance Officer shall maintain a license matrix tracking:

- License type and number by state
- Expiration dates and renewal deadlines (90-day advance notice to initiate renewal)
- Designated Representatives as required by state law
- Surety bond status and coverage amounts

2.4 Anti-Kickback Statute (AKS) Compliance

CRITICAL COMPLIANCE AREA — FEDERAL ANTI-KICKBACK STATUTE (42 U.S.C. § 1320a-7b(b))

Violation of the AKS is a federal felony punishable by imprisonment of up to 10 years per violation plus civil monetary penalties. All personnel must read, understand, and strictly comply with this policy.

No officer, manager, employee, contractor, or sales agent of Dermalynx Distribution shall offer, pay, solicit, or receive any remuneration (including kickbacks, bribes, or rebates) directly or indirectly, overtly or covertly, in cash or in kind, intended to induce or reward referrals of items or services covered by federal healthcare programs (Medicare, Medicaid, TRICARE, VA, etc.). Prohibited conduct includes:

- Offering or providing free products, services, or entertainment of more than nominal value to healthcare providers or their staff in exchange for, or with the intent to induce, product referrals or purchases;
- Paying commissions or bonuses tied to the volume or value of government healthcare program business;
- Providing consulting or medical director arrangements that are not commercially reasonable and at fair market value for actual services rendered;
- Forgiveness or reduction of co-payments, deductibles, or balances owed by Medicare/Medicaid beneficiaries;
- Offering equity or profit-sharing to referral sources in connection with federal healthcare program business.

The Company shall ensure that all sales representative agreements, consultant agreements, and distribution agreements include AKS compliance representations, compensation structures compliant with applicable safe harbors, and termination provisions for AKS violations.

2.5 Stark Law (Physician Self-Referral)

The Company shall not enter into financial relationships with referring physicians that violate the Physician Self-Referral Law (Stark Law, 42 U.S.C. § 1395nn) unless the arrangement falls within an applicable exception. All physician consulting agreements, advisory board arrangements, and vendor relationships involving physicians must be reviewed by qualified legal counsel prior to execution.

2.6 Government Contracting Compliance

For all sales to federal government agencies, the Company shall comply with:

- Federal Acquisition Regulation (FAR) — all applicable clauses incorporated by reference or explicitly in government contracts;
- Defense Federal Acquisition Regulation Supplement (DFARS) — for Department of Defense contracts;
- Trade Agreements Act (TAA) — only products from designated countries may be sold under GSA schedule contracts;
- System for Award Management (SAM.gov) — maintain current registration with annual renewal;
- Contractor Code of Business Ethics and Conduct (FAR 52.203-13) — implemented herein;

- Mandatory disclosure of credible evidence of violations of federal criminal law, civil False Claims Act, or the Procurement Integrity Act to the cognizant federal agency;
- Prohibition on doing business with excluded individuals or entities — monthly screening against the OIG Exclusions List and SAM.gov Exclusions.

SECTION 3 — QUALITY MANAGEMENT POLICY

POLICY 3.0

Quality Management System Policy

Rev. 1.0 | Effective: March 19, 2026 | Owner: Compliance & Quality Officer

3.1 Purpose

To establish and maintain a Quality Management System (QMS) that ensures all cellular tissue products distributed by Dermalynx Distribution, LLC meet applicable quality standards and that all distribution processes are controlled, documented, and continuously improved.

3.2 Storage and Temperature Control

The Company shall maintain storage conditions that meet the manufacturer's specifications and applicable regulatory requirements for all CTP products:

- Maintain temperature-controlled storage facilities with continuous temperature monitoring and documented alarm systems;
- All cold-chain products shall be stored within validated temperature ranges (refrigerated 2-8°C, frozen -20°C or -80°C as applicable) using calibrated equipment;
- Temperature excursion events shall be documented, reported to the relevant manufacturer, and resolved per written SOP;
- Third-party logistics (3PL) partners and shipping carriers shall be qualified and subject to written quality agreements specifying temperature control requirements.

3.3 Product Traceability and Chain of Custody

The Company shall maintain complete traceability of all HCT/P products from acquisition through distribution to the end recipient, including:

- Receipt documentation: lot number, expiration date, temperature upon receipt, condition, quantity, and manufacturer origin;
- Storage records: location assigned, temperature logs, inventory counts;
- Shipping records: recipient identity, shipping date, carrier, temperature at dispatch, lot numbers, quantities;
- Disposition records: product used, remaining inventory, expired product destruction documentation.

All traceability records shall be maintained for a minimum of ten (10) years. Electronic records shall be backed up and secured per the Information Security Policy (Section 7).

3.4 Product Recall Procedure

In the event of a product recall initiated by the manufacturer, the FDA, or the Company itself:

1. The Compliance/Quality Officer shall be notified immediately upon receipt of recall notification.
2. The Company shall identify all affected lot numbers in inventory and quarantine immediately.
3. All customers who received affected product shall be notified within 24 hours of Company receipt of recall notice.

4. A recall effectiveness check shall be conducted within 30 days to confirm recovery or disposition of all affected units.
5. A written recall report shall be prepared and retained in Company records.
6. FDA shall be notified as required under 21 CFR Part 7 and applicable recall guidance.

3.5 Supplier/Manufacturer Qualification

The Company shall distribute only from qualified, FDA-registered tissue establishments. Prior to entering a distribution agreement with a new manufacturer/supplier:

- Verify current FDA establishment registration;
- Obtain and review most recent FDA inspection results (Form 483 findings and any Warning Letters);
- Execute a written Distribution Agreement addressing quality standards, regulatory responsibilities, and recall obligations;
- Conduct periodic re-qualification not less than annually.

SECTION 4 — ANTI-BRIBERY & ANTI-CORRUPTION POLICY

POLICY 4.0

Anti-Bribery & Anti-Corruption Policy

Rev. 1.0 | Effective: March 19, 2026 | Owner: Compliance & Quality Officer

4.1 Purpose

To ensure compliance with the U.S. Foreign Corrupt Practices Act (FCPA), applicable domestic anti-bribery laws, and to maintain the Company's reputation for absolute integrity in all business dealings, including all transactions involving government officials.

4.2 Prohibition on Bribery

No Company personnel shall, directly or through any third party, offer, promise, pay, authorize the payment of, or accept any bribe or corrupt payment to or from any person, including:

- Any government official, employee, or agent (federal, state, local, or foreign);
- Any employee or agent of a healthcare organization, hospital, or purchasing group;
- Any private business entity or individual acting as a customer or supplier;
- Any political party, party official, or political candidate.

'Bribe or corrupt payment' means any item of value — including cash, gifts, entertainment, hospitality, travel, charitable donations, or other benefits — provided with the intent to improperly influence a business or government decision.

4.3 Gifts, Meals & Entertainment

All gifts, meals, and entertainment provided to or received from customers, suppliers, or government officials must comply with the following:

- Gifts to or from any single individual shall not exceed $25.00 in value per occurrence and $100.00 per calendar year;
- Business meals shall be modest, directly connected to a legitimate business discussion, and documented;
- No gifts, meals, or entertainment shall be offered to government officials without prior approval from the Compliance Officer;
- No cash or cash equivalents (gift cards, prepaid cards) shall be given as gifts under any circumstances;
- All entertainment and hospitality expenditures shall be documented with business purpose, attendees, and amounts.

SECTION 5 — HUMAN RESOURCES POLICIES

POLICY 5.0

Human Resources Policy Manual

Rev. 1.0 | Effective: March 19, 2026 | Owner: Compliance & Quality Officer

5.1 Equal Employment Opportunity

Dermalynx Distribution, LLC is an Equal Opportunity Employer. The Company does not discriminate on the basis of race, color, religion, sex, national origin, age, disability, genetic information, sexual orientation, gender identity, veteran status, or any other characteristic protected by applicable federal, state, or local law, in any aspect of employment including hiring, training, promotion, compensation, discipline, or termination.

5.2 Harassment-Free Workplace

The Company is committed to providing a work environment free from all forms of harassment, including sexual harassment. All employees and contractors are expected to treat colleagues, customers, and vendors with respect and professionalism. Any employee who believes they have experienced or witnessed harassment shall report it immediately to the Compliance Officer or via the confidential reporting hotline. Reports will be investigated promptly, and retaliatory action against any individual who reports in good faith is strictly prohibited.

5.3 Background Checks and OIG Exclusion Screening

All employees, contractors, and agents of the Company shall be subject to:

- Pre-hire criminal background check;
- Screening against the OIG List of Excluded Individuals and Entities (LEIE) prior to hire and monthly thereafter;
- Screening against SAM.gov System for Award Management exclusions;
- Verification of any required professional licenses or certifications.

Any individual who is excluded, debarred, suspended, or otherwise identified as ineligible to participate in federal healthcare programs shall not be employed or retained by the Company in any capacity.

5.4 Training Requirements

All personnel shall complete the following training upon hire and annually thereafter:

- This Corporate Policies & Procedures Manual (acknowledgment required);
- Code of Conduct (acknowledgment required);
- Anti-Kickback Statute and healthcare compliance fundamentals;
- HIPAA Privacy and Security (for any personnel with access to PHI);
- Government contracting ethics and False Claims Act;
- Product-specific training for all CTP categories distributed.

Training completion shall be documented and retained in personnel files for a minimum of six (6) years.

SECTION 6 — PRIVACY AND HIPAA COMPLIANCE POLICY

POLICY 6.0

Privacy & HIPAA Compliance Policy

Rev. 1.0 | Effective: March 19, 2026 | Owner: Compliance & Quality Officer

6.1 Applicability

As a distributor of CTP products to covered entities (hospitals, physicians, VA facilities), Dermalynx Distribution may act as a Business Associate under HIPAA in certain circumstances. The Company shall comply with all applicable requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act.

6.2 Protected Health Information

The Company shall not access, use, or disclose Protected Health Information (PHI) except as expressly authorized by applicable Business Associate Agreements (BAAs) and as permitted by HIPAA. Personnel shall not transmit PHI via unencrypted email, personal devices, or unsecured file sharing platforms.

6.3 Minimum Necessary Standard

All access to PHI shall be limited to the minimum information necessary to accomplish the intended purpose. Access shall be role-based and restricted on a need-to-know basis.

6.4 Data Breach Response

Any actual or suspected breach of PHI shall be immediately reported to the Compliance Officer. The Company shall conduct a risk assessment and, if breach notification is required, shall notify affected individuals, HHS, and any covered entity within the timeframes required by the HIPAA Breach Notification Rule (45 CFR Part 164, Subpart D).

SECTION 7 — INFORMATION SECURITY POLICY

POLICY 7.0

Information Security Policy

Rev. 1.0 | Effective: March 19, 2026 | Owner: Compliance & Quality Officer

7.1 Purpose

To protect the confidentiality, integrity, and availability of Company information assets, including customer data, financial records, regulatory submissions, product traceability records, and proprietary business information.

7.2 Access Controls

- All Company systems shall require unique user authentication credentials (username and strong password, minimum 12 characters);
- Multi-factor authentication (MFA) shall be required for all remote access to Company systems;
- Access privileges shall be assigned on the principle of least privilege and reviewed quarterly;
- Former employees' access shall be revoked on the last day of employment or contract termination.

7.3 Device and Data Security

- All laptops, mobile devices, and portable storage used for Company business shall be encrypted;
- Company data shall not be stored on personal devices without written authorization;
- Confidential data shall be transmitted only via encrypted channels (TLS/SSL);
- Data shall be backed up regularly and backups stored securely offsite or in a certified cloud environment.

7.4 Incident Response

Any suspected cybersecurity incident, unauthorized access, ransomware attack, or data breach shall be reported to management immediately. The Company shall maintain a written Incident Response Plan and conduct annual tabletop exercises.

SECTION 8 — CONFLICT OF INTEREST POLICY

POLICY 8.0

Conflict of Interest Policy

Rev. 1.0 | Effective: March 19, 2026 | Owner: Compliance & Quality Officer

8.1 Purpose

To ensure that all business decisions are made in the best interests of the Company and its customers, free from personal financial interests or relationships that could compromise or appear to compromise the exercise of independent judgment.

8.2 Disclosure Requirements

All employees and contractors shall promptly disclose to the Compliance Officer any actual, potential, or apparent conflict of interest, including:

- Financial interest in a customer, supplier, competitor, or other entity with which the Company does business;
- Employment or consulting relationships with competitors;
- Family members employed by customers, suppliers, or regulators;
- Receipt of gifts, entertainment, or benefits exceeding the limits in Section 4.3;
- Participation on any board of directors or advisory board of a healthcare entity.

8.3 Resolution

Disclosed conflicts shall be evaluated by the Compliance Officer and addressed through recusal, divestment, disclosure to affected parties, or other appropriate measures. The Company shall maintain a Conflict of Interest Disclosure Log.

SECTION 9 — RECORD RETENTION POLICY

POLICY 9.0

Record Retention Policy

Rev. 1.0 | Effective: March 19, 2026 | Owner: Compliance & Quality Officer

Record Category	Retention Period	Authority
HCT/P Traceability Records (donor to recipient)	**10 years**	*21 CFR § 1271.290*
FDA Establishment Registration	**Permanent**	*21 CFR § 1271.21*
Temperature/Storage Logs	**10 years**	*cGTP; 21 CFR § 1271.270*
Product Recall Records	**10 years**	*21 CFR Part 7*
Customer Sales Records	**7 years**	*IRS; FAR 4.703*
Government Contracts & Modifications	**7 years post-performance**	*FAR 4.703*
Employment Records	**7 years post-termination**	*EEOC; IRS*
Corporate Tax Returns	**7 years**	*IRS*
Operating Agreement & Articles	**Permanent**	*Company Policy*
Training Records	**6 years**	*OIG Guidance*
Compliance Program Records	**6 years**	*OIG Guidance; FCA*
Bank Records	**7 years**	*IRS*
Insurance Policies	**Permanent + 3 years**	*Company Policy*

Records subject to a legal hold, government investigation, or pending litigation shall not be destroyed regardless of the above schedule. The Compliance Officer shall issue litigation hold notices as circumstances warrant.

SECTION 10 — WHISTLEBLOWER & NON-RETALIATION POLICY

POLICY 10.0

Whistleblower & Non-Retaliation Policy

Rev. 1.0 | Effective: March 19, 2026 | Owner: Compliance & Quality Officer

10.1 Purpose

To encourage and protect employees, contractors, and agents who report in good faith concerns about potential violations of law, regulation, Company policy, or ethical standards, including concerns related to federal healthcare program fraud, waste, and abuse.

10.2 Reporting Channels

Any person may report concerns through the following channels:

- Directly to the Compliance Officer or any member of management;
- By written communication addressed to the Compliance Officer;
- Via any external reporting hotline designated by the Company;
- Externally to the Department of Health and Human Services Office of Inspector General (OIG) Hotline: 1-800-HHS-TIPS; or
- Via the SEC, DOJ, or other appropriate federal or state agencies if the concern involves federal violations.

10.3 Non-Retaliation

Retaliation against any individual who in good faith reports a concern, participates in an investigation, or refuses to participate in conduct believed to be unlawful is strictly prohibited and shall be grounds for immediate termination. This protection applies regardless of whether the reported conduct is ultimately found to constitute a violation.

10.4 False Reports

Knowingly making a false report is a violation of this Policy and may result in disciplinary action, up to and including termination. This Policy does not protect individuals who make reports with knowledge that they are false or with reckless disregard for their truth or falsity.

10.5 False Claims Act

The Company prohibits any submission of false or fraudulent claims to federal or state government programs. Employees are informed of their rights under the False Claims Act, 31 U.S.C. §§ 3729-3733, including the right to file a qui tam action and share in any government recovery.

SECTION 11 — GOVERNMENT CONTRACTING COMPLIANCE POLICY

POLICY 11.0
Government Contracting Compliance Policy
Rev. 1.0 | Effective: March 19, 2026 | Owner: Compliance & Quality Officer

11.1 Applicability

This Policy applies to all Company activities in connection with federal, state, or local government contracts, subcontracts, grants, and cooperative agreements, including contracts with the Department of Veterans Affairs, Department of Defense, Department of Health and Human Services, and any other federal agency.

11.2 SAM.gov and Registration Maintenance

The Company shall maintain a current, accurate, and complete registration in the System for Award Management (SAM.gov) including current Representations and Certifications. The registration shall be renewed annually and updated within 30 days of any material change.

11.3 Procurement Integrity

All personnel involved in federal procurements shall comply with the Procurement Integrity Act (41 U.S.C. § 2101 et seq.) including:

- No disclosure of contractor bid or proposal information to any person not authorized to receive it;
- No disclosure of source selection information before contract award;
- Prohibition on accepting certain employment discussions with a procurement official;
- Reporting of any violation to the agency contracting officer within 14 days.

11.4 Cost Allowability

All costs billed to government contracts must be allowable, allocable, and reasonable under applicable cost principles (FAR Part 31). The following costs are expressly unallowable on government contracts:

- Entertainment, alcohol, and personal expenses;
- Contributions and donations;
- Fines, penalties, and interest on late payments;
- Advertising costs (except for recruitment);
- Costs associated with a final criminal conviction;
- Costs related to a false claims violation.

11.5 Small Business Subcontracting

Where required by the terms of a government contract, the Company shall comply with applicable Small Business Act subcontracting requirements and shall not knowingly award subcontracts to large businesses in categories reserved for small businesses.

11.6 Trade Agreements Act (TAA) Compliance

For contracts subject to the TAA (generally contracts over the applicable threshold), the Company shall distribute only products that are manufactured in or substantially transformed in a TAA-designated country. Products from non-designated countries (e.g., China, India) may not be sold under TAA-covered contracts. The Compliance Officer shall maintain a TAA eligibility matrix for all product SKUs.

11.7 Organizational Conflicts of Interest

The Company shall promptly identify and disclose to the Contracting Officer any actual, potential, or apparent Organizational Conflict of Interest (OCI) as defined in FAR Subpart 9.5. The Company shall not pursue a contract where an unmitigated OCI exists.

11.8 Mandatory Disclosure

As required by FAR 52.203-13, the Company shall promptly disclose to the agency Inspector General and the Contracting Officer any credible evidence of a principal, employee, agent, or subcontractor committing a violation of federal criminal law involving fraud, conflict of interest, bribery, or gratuity, or a violation of the civil False Claims Act. Disclosure shall be made in writing within a reasonable time after discovery.

SECTION 12 — POLICY ACKNOWLEDGMENT

All employees, contractors, and agents of Dermalynx Distribution, LLC are required to read this Corporate Policies & Procedures Manual and sign the acknowledgment below. Signed acknowledgments shall be retained in personnel files.

ACKNOWLEDGMENT OF RECEIPT

I, the undersigned, acknowledge that I have received, read, and understood the Dermalynx Distribution, LLC Corporate Policies & Procedures Manual (Revision 1.0). I agree to comply with all policies, procedures, and standards set forth therein. I understand that violation of these policies may result in disciplinary action up to and including termination of my employment or engagement.

_____

Printed Name

_____

Signature

_____

Title / Role

_____

Date

— END OF CORPORATE POLICIES & PROCEDURES MANUAL —