Guardrails That Work: Practical Reimbursement Rules for the Field

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Agenda

- Introductions
- Why reimbursement support is legally sensitive
- Legal and compliance framework (AKS, FCA, FDA, HIPAA)
- Program models and operational design
- Sales and reimbursement guardrails
- Field dos and don’ts and real-world missteps
- How it all fits together and takeaways

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About Gardner Law

Gardner Law provides expert counsel to FDA-regulated companies on regulatory, compliance, privacy, and litigation matters.

Our industry and government experience enables us to deliver actionable advice, empowering clients to make informed decisions.

We prioritize responsiveness, ensuring timely support. Our attorneys possess deep regulatory knowledge gained through experience at leading organizations.

Legal Practice Areas:

- Regulatory
- Compliance
- Privacy
- Litigation
- Commercial Transactions

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Presenter Introduction

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Mark Gardner counsels FDA-regulated companies on compliance, regulatory, privacy, and litigation matters.

- 25 years working in healthcare industry
- Adjunct Professor at University of Minnesota Law School
- Adjunct Professor at Mitchell Hamline School of Law
- Adjunct Professor at Carlson School of Management
- Former ev3, Celleration, MedTox Laboratories
- Co-founder of JDL Access

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Presenter Introduction

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Amanda Johnston is a distinguished FDA attorney with expertise in counseling medical device and pharmaceutical companies on FDA law, regulatory strategy, and healthcare compliance matters.

- Medicare Compliance at UnitedHealth Group
- Regulatory at Medtronic Neuromodulation
- Led North America Compliance at Coloplast
- Adjunct professor of Drug and Device Law at Mitchell Hamline
- 2023, 2024, 2025 Rising Star, Super Lawyers
- 2023 Women in Business Honoree, Minneapolis-St. Paul Business Journal

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Presenter Introduction

Kim Norton
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Kim Norton has worked in medical technology reimbursement for over 30 years, with a singular focus on helping patients gain access to novel and innovative technologies. She now leads JDL Access with that same focus: ensuring that patients have choices when it comes to their health care treatment.

- 30 years in medical technology reimbursement and patient access
- Helped establish coverage for numerous new medical devices
- Deep industry experience, including managing patient support programs

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About JDL Access

Established to provide integrated reimbursement support and patient access services to the medical technology industry

As payers continue to create barriers to emerging technologies, our mission is to continue to provide best-in-class support to patients and, ultimately, to help establish positive medical policies

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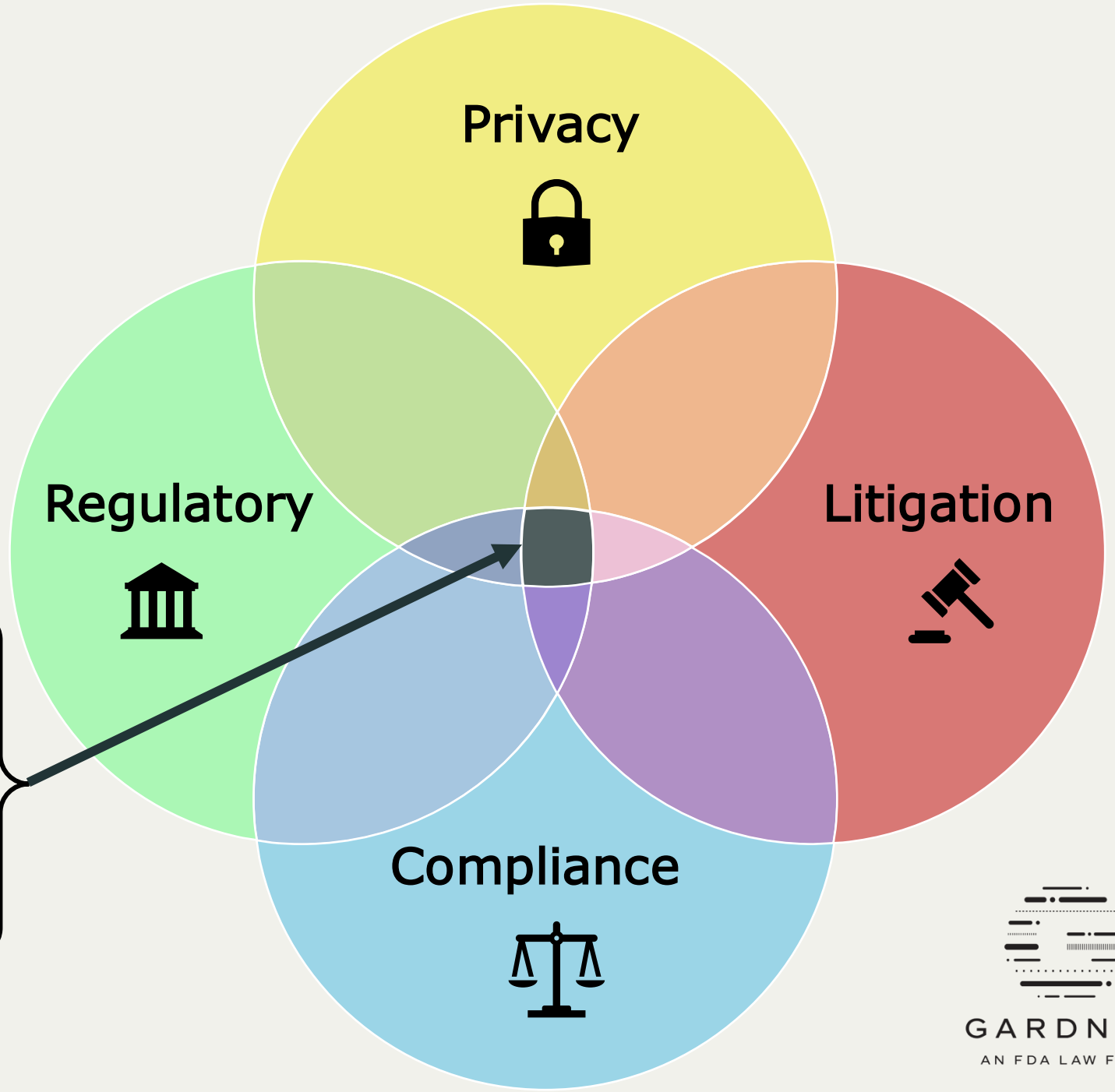
Legal Landscape



Reimbursement support programs touch many areas of law, requiring careful navigation of privacy, regulatory, compliance, and litigation risks.

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Fraud, Abuse, & FDA Risks

Anti-Kickback & False Claims Act (AKS/FCA)

- It is illegal to provide anything of value to influence the purchase, prescription, or use of items reimbursed by federal healthcare programs
- Manufacturers can face liability if their actions cause or induce false claims
- Incorrect or inappropriate reimbursement support can create AKS and FCA exposure, including significant penalties and exclusion

FDA Promotion Considerations (FDCA)

- FDA regulates how drugs and devices are manufactured and promoted
- Facilitating and providing reimbursement support for off-label uses could be viewed as off-label promotion

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Privacy and HIPAA Risks

HIPAA & Patient Data

- Protected Health Information (PHI) includes patient-identifiable health and payment information
- Patient access and reimbursement support activities frequently involve PHI (e.g., prior authorizations, appeals, coverage verification)

Compliance Considerations

- Establish a HIPAA-compliant basis for using and sharing PHI (e.g., business associate agreement or patient authorization, as appropriate)
- Implement and maintain appropriate privacy and data-security safeguards
- Comply with applicable state privacy laws and institutional policies
- Access to payer portals and electronic transactions is role- and fact-specific and may depend on how the program is structured and contractually authorized. Legal review is recommended.

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Why Sales/Reimbursement Separation Matters

Why this matters

- Reimbursement support helps patients access therapy
- Sales teams drive demand and revenue
- Blurring the roles creates AKS, FCA, and FDA risk

Key risk drivers

- Sales influence over coverage, coding, or documentation
- Perception that reimbursement support is a sales tool
- Inconsistent or undocumented handoffs between teams

Core principle: Reimbursement support exists to support patient access, not to close sales.

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What Are Reimbursement Support Programs?

- Patient access services help navigate insurance coverage on a case-by-case basis
- Bridge between patients, providers, and payers to ensure treatment access to innovative technologies
- Support services include benefits verification, prior authorization assistance, appeals support
- Why on behalf of patients? To get cases out to external review, which is a patient right protected by the ACA to enable an independent review; every time a case goes to an independent review organization (IRO), the payer of record is responsible for the cost
- Goal: Remove barriers to access by getting individual cases overturned and putting pressure on payers as a result to develop positive medical policies

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In-House vs. Third Party Reimbursement Support

- **In-House Reimbursement Support**
  - Greater control over workflows, escalation, and oversight
  - Requires internal investment in staffing, training, and compliance infrastructure
  - Heightened need for strong internal guardrails separating sales and reimbursement functions
  - Responsibility for privacy, security, and audit readiness remains fully internal
- **Third-Party Reimbursement Support**
  - Leverages external expertise and established reimbursement operations
  - Faster implementation with less internal infrastructure buildout
  - Requires robust vendor diligence, contracting, and ongoing oversight
  - Manufacturer retains accountability for compliance, even when functions are outsourced
- **Key takeaway:** Both models can be compliant. Risk depends on structure, controls, and oversight, not whether the function is in-house or outsourced.

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How Do You Ensure A Compliant Program?

- Clear policies and procedures that comply with Anti-Kickback Statute and False Claims Act
- Strict separation between commercial and clinical functions
- PHI protection measures (HIPAA compliance)
- Transparent patient consent processes
- BAAs with third-party vendors
- Train staff continuously on compliance requirements and privacy obligations
- Audit trails and documentation protocols
- Escalation procedures for compliance concerns
- Regular compliance monitoring and program audits

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How Do You Enforce Compliant Sales Team Interactions?

- Data segregation: As a general rule, sales teams should not have access to PHI
- Sales should receive only de-identified, aggregated data
- One-way referral process: Sales refers to reimbursement, not vice versa
- No sales compensation tied to patient enrollments or outcomes
- Prohibition on sales using reimbursement support as inducement
- Regular training on appropriate interactions
- Technology controls to enforce access restrictions

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How Does JDL Access Help MedTech Companies Establish Internal Support Programs?

Core Compliance Feature: Cloud-based external platform keeps PHI outside company infrastructure

Data isolation: Patient data not in internal CRM system (can API to CRM but block PHI)

Role-based access controls

Built-in audit logging for all data access and changes

Enforces separation between sales and patient support functions

Reduces company's internal PHI risk exposure

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How Does JDL Access Help MedTech Companies Establish Internal Support Programs? (Cont.)

Compliance Focus: HIPAA Policies, Training, and Auditing

We utilize a compliance partner to help us manage this

We educate our clients about the benefit of this type of partnership

We help our clients understand the PHI risks and how to mitigate them, especially with remote employees

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Clear Role Separation

Sales Team – Permitted Role

- Educate on product features, indications, and approved use
- Identify that reimbursement support is available
- Refer providers or staff to reimbursement support resources
- Stay high-level on coverage landscape (no payer-specific promises)

Reimbursement Support – Permitted Role

- Coverage verification and prior authorization support
- General coding education
- Appeals support based on published policies
- Administrative assistance using provider-supplied information

Key guardrail: Sales should connect, not control, reimbursement activities.

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Common Field Missteps

- What we see go wrong
  - Sales reps suggesting specific codes
  - Editing, drafting, or coaching on medical records or other claims document language
  - Promising coverage or reimbursement outcomes
  - Sitting in on PA or appeal calls with payers
  - Acting as the "go-between" for payer communications
  - Retaining copies of documents containing PHI
  - Helping provider offices complete authorization forms

Why this is risky

- Creates inducement and false claims exposure
- Undermines provider independence
- Leaves no defensible compliance narrative

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Sales Team Dos and Don’ts

- **DO**
  - Direct providers to reimbursement support teams
  - Use approved scripts and escalation pathways
  - Stick to general education on coverage processes
  - Document handoffs appropriately

- **DON’T**
  - Recommend codes, modifiers, or documentation language
  - Complete or edit medical records or PA forms
  - Communicate directly with payers about coverage
  - Store or transmit PHI outside approved systems
  - Frame reimbursement support as a “sales advantage”

Guardrails Around Coding, Coverage, and Documentation

- Coding
  - High-level education only
  - No code selection or payer-specific advice by sales
  - Use approved coding resources
- Coverage
  - No guarantees or predictions
  - Coverage varies by payer and patient
  - Reimbursement support may explain policies, not outcomes
- Documentation
  - Providers are solely responsible for medical necessity
  - No sales involvement in charting, notes, or appeals language
  - Clear audit trail of who did what

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Communications & Escalation Guardrails

Field communications

Use approved templates and scripts

Avoid informal texts or emails discussing reimbursement strategy

No “workarounds” suggested

Escalation

Questions about coverage, coding, or denials → reimbursement support

Gray areas or unusual requests → legal/compliance review

Key takeaway

Structure, documentation, and discipline protect both access and the company.

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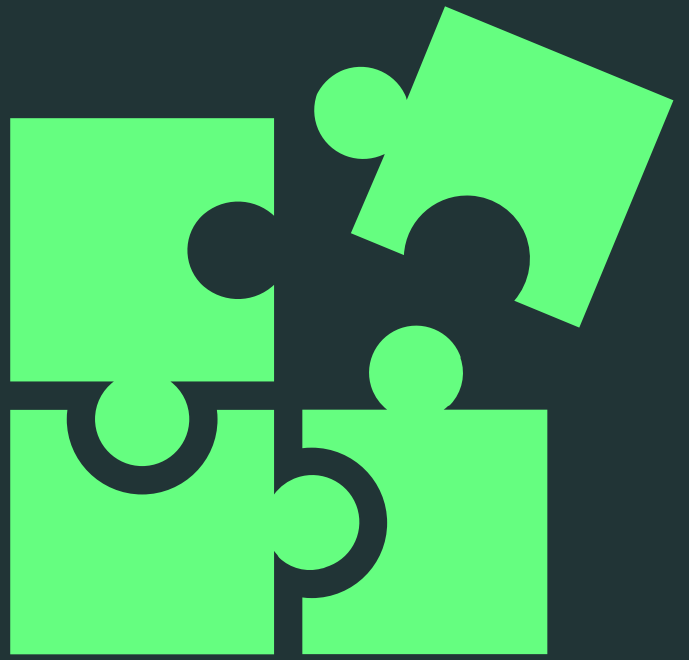
How This All Fits Together

Building a Compliant Reimbursement Support Program

1. Select the Right Program Model
2. Design Compliant Operations
3. Define Clear Roles and Boundaries
4. Apply Practical Field Guardrails
5. Monitor, Document, and Adjust

Key takeaway: Thoughtful structure, clear guardrails, and disciplined execution enable patient access while standing up to regulatory scrutiny.



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Key Takeaways

- Reimbursement support programs are essential for patient access but must be designed with compliance at the core
- Strict separation between commercial and patient support functions is a foundational compliance expectation
- Technology architecture matters: external platforms reduce risk and enforcement burden
- Sales teams can work effectively with limited, de-identified data
- Practical guardrails enable both patient access and regulatory compliance

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Questions?


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