Governance Brief No. 1
Board Considerations Before Adopting LLM-Based Clinical Tools

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Purpose

This memorandum outlines governance considerations for healthcare organizations evaluating the use of Large Language Model (LLM)–based tools in clinical workflows.

LLM tools are increasingly marketed as documentation assistants, decision-support systems, and workflow enhancers. While these systems may improve efficiency and consistency, their integration introduces operational, regulatory, and liability considerations that require board-level oversight.

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1. Clarify the Functional Role of the Tool

Before adoption, the Board should require management to clearly define:

• Is the tool assistive, advisory, or decision-influencing?
• Does it summarize clinician input, or generate diagnostic or treatment suggestions?
• Does it operate in real time during patient encounters?
• Is it embedded in the EHR or functioning externally?

Terminology (AI vs. LLM vs. clinical intelligence) does not determine risk exposure. Functional impact does.

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2. Clinical Judgment and Accountability

The Board should confirm:

• The clinician retains final authority over diagnosis and treatment decisions.
• Policies require documented independent review before AI-generated content is signed.
• There is no workflow design that incentivizes passive acceptance of system outputs.
• Performance metrics do not unintentionally reward throughput at the expense of review quality.

Liability remains attached to professional judgment, regardless of tool assistance.

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3. Validation and Performance Testing

Management should present documentation addressing:

• Validation of the tool within the organization's patient population.

• Accuracy rates in speech-to-text transcription (if applicable).
• Performance across diverse accents and communication styles.
• Known limitations and error patterns.
• Ongoing performance monitoring protocols.

If the system influences clinical documentation or reasoning, local validation is essential.

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4. Documentation Integrity and Audit Trail

The Board should require:

• Clear differentiation between clinician-authored content and AI-generated content within the record.
• An auditable log of AI interactions influencing documentation or recommendations.
• Ability to reconstruct what the system suggested and what the clinician accepted or rejected.
• Periodic internal audit review of AI-assisted encounters.

Transparency protects both patient safety and institutional defensibility.

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5. Informed Consent and Patient Transparency

Consideration should be given to:

• Whether patients are informed that AI-assisted tools are used in documentation or care planning.
• Whether state law or regulatory guidance requires disclosure.
• Alignment with institutional ethics standards.

Transparency strengthens trust.

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6. Data Privacy and Security

Boards should ensure management has addressed:

• HIPAA compliance and Business Associate Agreements.
• Data storage location and cross-border processing.
• Secondary use of clinical data for model training.
• Cybersecurity controls specific to third-party AI vendors.

Technology integration expands the risk surface.

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7. Vendor Risk and Indemnification

The Board should understand:

• Vendor liability limitations in contractual agreements.
• Indemnification provisions.
• Allocation of responsibility in adverse outcome scenarios.
• Insurance coverage implications.

In many contracts, vendors limit exposure for clinical outcomes.

The organization must understand where exposure ultimately resides.

8. Ongoing Governance Structure

Adoption should not be treated as a one-time decision.

Boards should require:

• A formal AI governance committee or oversight function.
• Defined reporting cadence to executive leadership and the Board.
• Periodic re-validation as models are updated.
• Incident reporting specific to AI-related errors.

Capability evolves. Oversight must evolve with it.

Strategic Framing

LLM-based clinical tools may provide:

• Reduced documentation burden
• Improved standardization
• Enhanced compliance monitoring
• Decision-support augmentation

These benefits are real.

However, augmentation must not evolve into automation without corresponding control structures.

Technology expands capacity. It does not transfer accountability.

Closing Observation

Whether described as AI, LLM, or clinical intelligence, tools that influence clinical judgment require structured oversight.

Renaming a system does not change its risk profile.

Governance must focus on:

Function
Control
Validation
Auditability
Accountability

Boards that address these issues proactively will strengthen both patient trust and organizational resilience.

Boards evaluating AI-enabled clinical tools may benefit from an independent governance perspective prior to deployment.

A structured external review often surfaces gaps that are easy to miss during implementation planning.