EU AI Act Applicability Memo

ClearPath Pharmacy: AI Governance Portfolio

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AI system in scope	Patient Adherence and Outreach Prioritization (AOP) tool

From: Information Security & Compliance Department **To:** Information Security Steering Committee

Re: Applicability of Regulation (EU) 2024/1689 (the EU AI Act) to the Patient Adherence and Outreach Prioritization (AOP) tool

1. Summary

On its current facts, the EU AI Act does not directly apply to ClearPath Pharmacy, because ClearPath operates only in the United States and neither places the AOP tool on the EU market nor produces outputs used by people in the EU. This memo nonetheless classifies the system as if the Act applied, because the high-risk analysis is a useful governance benchmark and shows the program can reason across regulatory regimes.

2. Territorial Scope (does the Act reach ClearPath?)

- The Act applies to providers placing AI systems on the EU market, deployers established or located in the EU, and providers or deployers whose AI output is used in the EU.

- ClearPath Pharmacy is a US specialty pharmacy serving US patients; it is a deployer of a US-hosted tool with no EU establishment, EU patients, or EU-directed output.
- Conclusion: the Act does not currently apply. Re-evaluate if ClearPath expands to EU patients or partners.

3. Hypothetical Risk-Tier Classification

The Act uses four risk tiers: unacceptable, high, limited, and minimal. Assessed against the AOP tool:

Tier	Applies?	Reasoning
Unacceptable	No	The tool is not a prohibited practice (no social scoring, manipulation, or biometric categorization of protected traits).
High-risk	Likely, if deployed in the EU	Annex III covers AI used in access to essential private and public services, including healthcare. A tool that influences which patients receive care outreach would likely be assessed as high-risk.
Limited	Possible alternative	If positioned purely as internal workflow prioritization with no effect on access to care, a limited-risk (transparency-only) reading is arguable but weaker.
Minimal	No	The patient-affecting nature rules out the minimal tier.

4. Obligations If Treated as High-Risk

If the AOP tool were high-risk under the Act, the deployer and provider obligations would include:

☐ A risk management system across the lifecycle.

☐ Data governance, including representative, relevant, and bias-checked training data.

☐ Technical documentation and automatic logging (traceability).

☐ Transparency and clear information to deployers and affected persons.

☐ Human oversight by design.

☐ Accuracy, robustness, and cybersecurity.

☐ Conformity assessment and registration before placing on the market.

5. Cross-Regime Observation

Most of these obligations already map to work recommended in the NIST AI RMF Profile and the ISO/IEC 42001 Gap Analysis: risk management, data governance, human oversight, logging, and transparency. A single, well-built AI governance program satisfies NIST, ISO, and the EU AI Act's high-risk core at once. Where the AOP tool processes PHI, HIPAA sits on top of all of them.

6. Recommendation

1. Record that the EU AI Act does not currently apply, and set a trigger to reassess on any EU expansion.
2. Proceed with the NIST and ISO remediation work, which also covers the Act's high-risk core if it ever applies.