Ainsley Advisory Group
A BOUTIQUE HEALTHCARE AI FIRM

AI Startup Regulatory Readiness Checklist

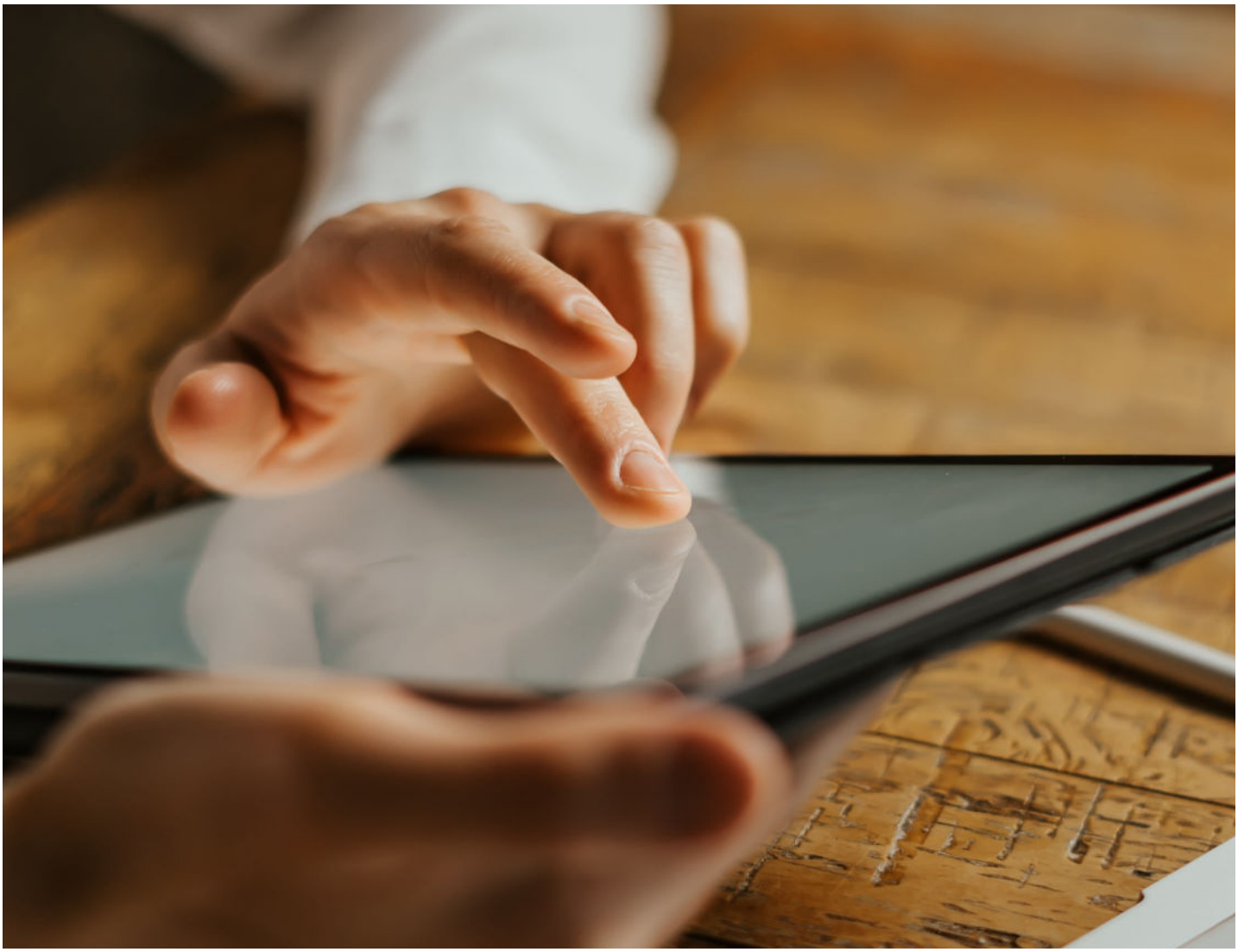
How to Stop Guessing and Start Navigating Healthcare AI Compliance with Confidence

What This Is

If you're building an AI solution for healthcare, you're entering a world of acronyms, ambiguity, and red tape. And let's be real—it's not something you can "figure out later."

This checklist is designed for startup founders who want to understand where they stand—and what steps come next. No legalese. No filler. Just clear checkpoints across the three pillars of healthcare AI compliance: **Privacy (HIPAA), Safety (FDA), and Payment/Policy (CMS)**.

Use this to get your house in order before investor diligence, pilot outreach, or clinical validation planning. And if you need help bridging the gaps—we're one call away.



HIPAA - Health Data Privacy & Security

Are You...

- [ ] Collecting or storing Protected Health Information (PHI) in your platform or model inputs?
- [ ] Encrypting data both at rest and in transit?
- [ ] Using a HIPAA-compliant cloud infrastructure (e.g., AWS/GCP with a signed BAA)?
- [ ] Limiting access to PHI based on job roles and clinical necessity?
- [ ] Logging and auditing user access to PHI in your system?
- [ ] Documenting how you handle consent, data de-identification, or data minimization?

If you checked fewer than 4, you may not be HIPAA-ready. Let's fix that before a health system or investor finds the gaps.

FDA - Clinical Safety & Model Validation

Does Your AI...

- [ ] Make predictions or recommendations that influence clinical decision-making?
- [ ] Require real-time input from patient data or electronic medical records (EMRs)?
- [ ] Fall under the FDA's Software as a Medical Device (SaMD) category?
- [ ] Have a clearly defined intended use case (diagnosis, triage, prioritization, etc.)?
- [ ] Use training and test data that reflects real-world clinical variation?
- [ ] Have documentation on model performance: sensitivity, specificity, AUC, etc.?
- [ ] Show your plans for ongoing monitoring, drift detection, or human oversight?

If any of this sounds unfamiliar, your model may need a regulatory strategy before you talk pilots or publish results.

CMS & Reimbursement Readiness

Have You...

- [ ] Identified whether your solution aligns with value-based care models?
- [ ] Considered how your tool may be billed (e.g., under CPT codes or new tech add-ons)?
- [ ] Explored how health systems might achieve cost savings or efficiency with your product?
- [ ] Mapped your AI's outcomes to any quality metrics or risk stratification frameworks?
- [ ] Prepared a reimbursement narrative—or are you relying on "we'll figure it out later"?

Health systems won't adopt what they can't justify. We help startups build the reimbursement story investors and buyers want to hear.

Final Scorecard

HIPAA:_____/6 FDA:_____/7 CMS:_____/5

Total:_____/18

Score Guide

15–18

You're ahead of the curve—likely ready for pilot conversations.

10–14

You've got momentum, but there are gaps to close fast.

<10

Pause. This needs strategic attention before you move forward.

Need help filling the gaps?

We offer targeted compliance audits, regulatory playbooks, and go-to-market strategies tailored for early-stage AI teams.

Let's make sure you're not one misstep away from a "no."

Request a 1:1 Compliance Consult Today

Reach Out Today