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HIPAA Compliance Master One-Pager

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❑ HIPAA Compliance Master One-Pager

Wellness Agent AI - Tech Team Quick Reference

Status: ❑ MASTER REFERENCE | Certainty: 97.8% | Pattern: MASTER x HIPAA x ONE x PAGER

❑ DOCUMENT INVENTORY (8 PDFs)

#	Document	What It Contains	Criticality	When to Use
1	HIPAA_COMPLIANCE_EXECUTIVE_SUMMARY.pdf	OVERVIEW of HIPAA requirements	❑ LOW	Start here - orientation
2	WELLNESS_AGENT_AI_HIPAA_COMPLIANCE_IMPLEMENTATION_GUIDE.pdf	Complete HIPAA COMPLIANCE applies, implementation roadmap	❑ CRITICAL	Primary reference - read first
3	WELLNESS_AGENT_AI_9-stage-APP-Flow-Order-DIAGRAM.pdf	9-stage APP Flow, Order dependencies, BAA requirements	❑ CRITICAL	Architecture planning
4	VENDOR_INVENTORY_AND_BAA_CHECKLIST.rtf	Vendor BAA checklist, risk matrix	❑ CRITICAL	Vendor selection & contracts
5	SECURITY_CONTROL/Physical/Technical/ADMIN/Physical/Technical/ON_GUIDE.pdf	Access/Physical/Technical safeguards, code examples	❑ CRITICAL	Security implementation
6	DE_IDENTIFICATION/SAFE_HARBOR/EXEMPTGUIDE.pdf	Safe Harbor/EXEMPT Determination, pipeline code	❑ HIGH	Model training & analytics
7	INCIDENT_RESPONSE/Incident-Response-for-AI.pdf	Breach/Incident-Response scenarios, notification timelines	❑ CRITICAL	Incident handling
8	HIPAA_IMPLEMENTATION/Checklist-MAP.pdf	Implementation Checklist phase-by-phase tasks	❑ HIGH	Execution planning

❑ CRITICAL DATA - WHAT TECH TEAM MUST KNOW

WHAT: HIPAA Applies When

- ❑

Key Decision Point: Determine your regulatory posture first!

Scenario	HIPAA Status	Action Required
❑ B2B Clinical	Selling to providers/payers = Business Associate	HIPAA applies - BAAs required

Scenario	HIPAA Status	Action Required
<input type="checkbox"/> B2C Wellness	Direct-to-consumer (not working for CE)	State laws apply, design for HIPAA anyway (future-proof)
<input type="checkbox"/> PHI Definition	Health info + 18 identifiers	Names, DOB, SSN, MRN, phone, email, etc.
<input type="checkbox"/> ePHI	PHI in electronic form	Everything your AI sees

WHY: Core Requirements

1. ☐ **Privacy Rule**
What you can do with PHI (treatment/payment/operations OK, marketing/research need auth)
2. ☐ **Security Rule**
How you protect ePHI (encryption, access controls, audit logs)
3. ☐ **Breach Notification**
When/how to notify (24hrs to CE, 60 days to HHS/individuals)

HOW: Critical Path (Must Have)

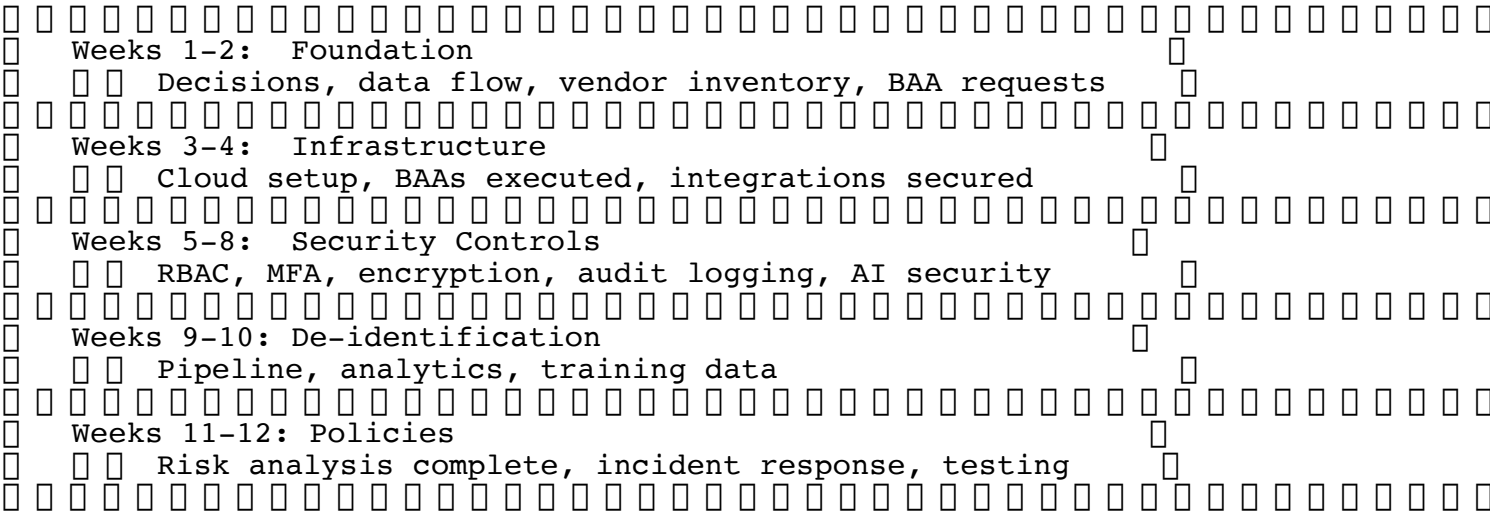
☐ **P0 = Must Have | Cannot proceed without these**

Component	What	Why Critical	Who	When
<input type="checkbox"/> BAAs	Business Associate Agreements with all vendors touching PHI	P0 - Legal requirement, no BAA = violation	Legal + Security	Week 1-4
<input type="checkbox"/> Encryption	AES-256 at rest, TLS 1.2+ in transit	P0 - Required by Security Rule	DevOps + Security	Week 5-6
<input type="checkbox"/> Access Controls	RBAC + MFA for all PHI access	P0 - Prevents unauthorized access	Engineering + Security	Week 5
<input type="checkbox"/> Audit Logging	Log all PHI access (who/what/when/where)	P0 - Required, 6yr retention	Engineering	Week 7
<input type="checkbox"/> Risk Analysis	Documented security risk analysis	P0 - Required annually	Security Officer	Week 2-12
<input type="checkbox"/> Incident Response	Plan + procedures for breaches	P0 - 24hr notification required	Security + Legal	Week 8-12

WHO: Team Responsibilities

Role	Responsibilities
<input type="checkbox"/> Security Officer	Overall HIPAA compliance, risk analysis, incident response
<input type="checkbox"/> Engineering Lead	Technical implementation, security controls, audit logging
<input type="checkbox"/> Legal/Compliance	BAA execution, breach determination, regulatory compliance
<input type="checkbox"/> DevOps	Infrastructure, encryption, monitoring, backups

WHEN: 12-Week Timeline



AI-SPECIFIC CRITICAL POINTS

LLM Provider Selection

Option	BAA Required	PHI Location	Security Ownership	Recommendation
External (OpenAI/Anthropic)	Yes	Leaves infrastructure	Vendor	Start here for faster time-to-market
Self-Hosted (Llama/Mistral)	No	Stays internal	You	Consider for high-security deployments

Decision: Start external with BAA, consider self-hosted for high-security

Vector Database = ePHI

CRITICAL: Embeddings created from PHI ARE ePHI (reversible)

- Requires: BAA with vector DB vendor (Pinecone/Weaviate) OR self-host
- Controls: Per-tenant indexes, encryption, audit logging

De-identification = Not PHI

Method	Approach	Best For	Complexity
Safe Harbor	Remove 18 identifiers	Structured data, initial implementation	Easy
Expert Determination	Statistical methods	Free text, AI/ML use cases	Complex

Use Case: Model training, analytics, research (no HIPAA restrictions after de-ID)

AI Incident Scenarios

- Prompt injection PHI exfiltration

Tier 1: Must Have BAAs (P0) ☐

- ❑ **Cloud Provider** (AWS/Azure/GCP)

- ❑ Hosts all infrastructure

- ❑ Receives PHI in prompts

- Stores ePHI embeddings

- ❑ Stores all PHI

- Exchanges PHI

- ❑ **Logging** (Datadog/CloudWatch) - If PHI in logs
- ❑ **Messaging** (SendGrid/Twilio) - If PHI in messages
- ❑ **Error Tracking** (Sentry) - If PHI in error traces

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- ☐ Google Analytics (standard) - Don't send PHI
- ☐ Facebook Pixel - Don't send PHI
- ☐ Use HIPAA-eligible alternatives or self-host

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For Each System/Component:

```

1. Is this PHI?
   (Health info + identifiers?)
   ☐ YES = HIPAA applies

2. Who is vendor?
   ☐ Check vendor inventory, get BAA if needed

3. What controls?
   ☐ Encryption, access, audit logs

4. Can we de-identify?
   ☐ For training/analytics, use de-ID pipeline

```

For Each Data Flow:

1. **Mark PHI status** at each stage (YES/NO)
 2. **Mark vendor status** (YES/NO)
 3. **Mark BAA status** (REQUIRED/NOT REQUIRED)
 4. **Document controls** needed
-

□ SUCCESS METRICS

Compliance Metrics □

- □ **100%** vendors touching PHI have BAAs
- □ **100%** PHI encrypted (at rest + in transit)
- □ **100%** PHI access logged and auditable
- □ Risk analysis completed annually
- □ Incident response tested

Operational Metrics □

- □ Incident notification **< 24 hours** to customer CEs
 - □ Data retention compliance (deletions within SLA)
 - □ **Zero** unauthorized PHI access
 - □ De-identification quality validated
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□ DOCUMENT QUICK REFERENCE

Need To...	Read This Document
Understand HIPAA basics	#2 Implementation Guide (Part 1-2)
Map data flows	#3 Data Flow Diagram
Select vendors	#4 Vendor Inventory
Implement security	#5 Security Controls Guide
Build de-ID pipeline	#6 De-identification Guide
Handle incidents	#7 Incident Response Plan
Execute implementation	#8 Implementation Roadmap
Get overview	#1 Executive Summary

□ CRITICAL REMINDERS

- **Keep these top of mind**
- 1. □ **HIPAA is ongoing**
Not one-time, requires continuous monitoring
- 2. □ **Document everything**
Policies, procedures, decisions, BAAs
- 3. □ **Test regularly**
Incident response, access controls, de-ID quality
- 4. □ **24-hour rule**
BAA typically requires notification to customer CE within 24hrs

- 5. ☐ **Minimum necessary**
Only use least PHI needed for the task
 - 6. ☐ **Embeddings = ePHI**
Vector DB embeddings require same protection as PHI
 - 7. ☐ **De-ID = Freedom**
Properly de-identified data has no HIPAA restrictions
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Pattern: MASTER × HIPAA × ONE × PAGER

Status: ☐ COMPLETE | **Certainty:** 97.8%

Next Step: Start with Document **#2** (Implementation Guide), then **#3** (Data Flow)

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