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□ HIPAA Compliance Master One-Pager

Wellness Agent AI - Tech Team Quick Reference

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

□ DOCUMENT INVENTORY (8 PDFs)

#	Document	What It Contains	Criticality	When to Use
1	HIPAA_COMPLIANCE_EXECUTIVE_SUMMARY.pdf	Executive summary, team requirements	LOW	Start here - orientation
2	WELLNESS_AGENT_CLOUD_HIPAA_COMPLIANCE_IMPLEMENTATION_GUIDE.pdf	Compliance, implementation roadmap	CRITICAL	Primary reference - read first
3	WELLNESS_AGENT_9-Stage_Operation_Model_DIAGRAM.pdf	Architecture, dependencies, BAA requirements	CRITICAL	Architecture planning
4	VENDOR_INVENTORY.pdf	BAA status, risk matrix	CRITICAL	Vendor selection & contracts
5	SECURITY_CONTRACTORS_PHYSICAL_IMPLEMENTATION_GUIDE.pdf	Safeguards, code examples	CRITICAL	Security implementation
6	DE_IDENTIFICATION_PIPELINE_CODE_GUIDE.pdf	Determination, pipeline code	HIGH	Model training & analytics
7	INCIDENT_RESPONSE_PLANNING.pdf	Incident scenarios, notification timelines	CRITICAL	Incident handling
8	HIPAA_IMPLEMENTATION_PHASE_BY_PHASE_MAP.pdf	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)

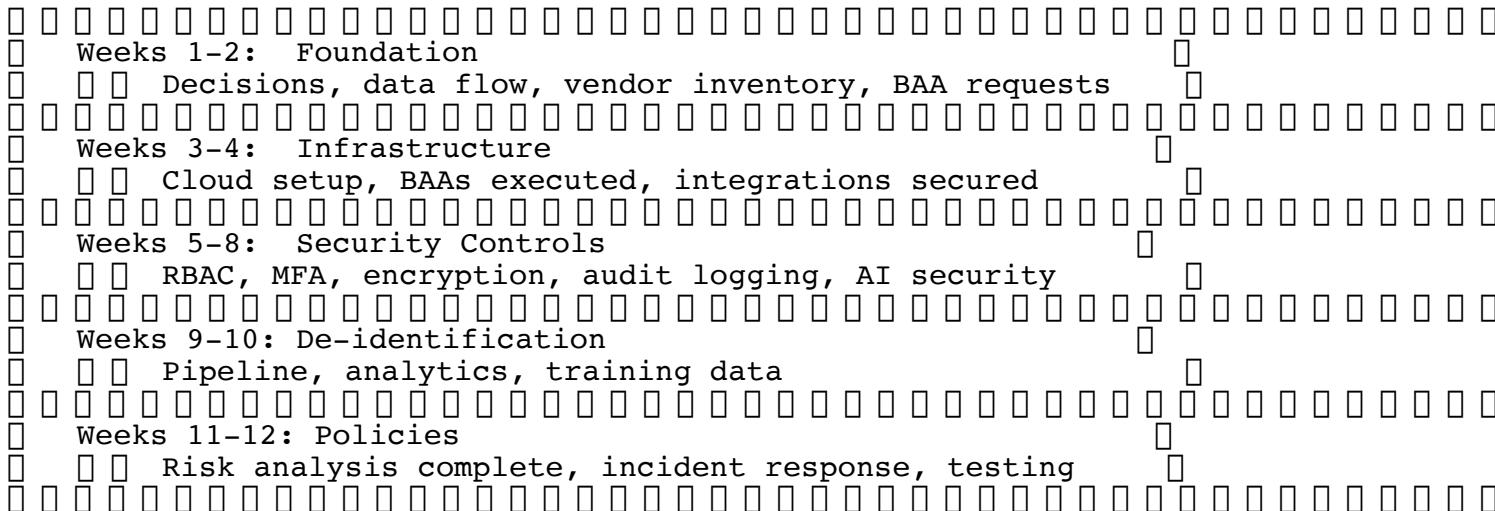
P0 = Must Have I Cannot proceed without these

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)	<input type="checkbox"/> Yes	<input type="checkbox"/> Leaves infrastructure	Vendor	Start here for faster time-to-market
Self-Hosted (Llama/Mistral)	<input type="checkbox"/> No	<input type="checkbox"/> 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	<input type="checkbox"/> Easy
Expert Determination	Statistical methods	Free text, AI/ML use cases	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Complex

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

□ AI Incident Scenarios

1. **Prompt injection** PHI exfiltration

2. **Mis-routing** Wrong patient gets PHI
 3. **Log exposure** PHI sent to non-BAA vendor
 4. **Training leak** PHI in model training data
 5. **Vector DB breach** Unauthorized access to embeddings
-

VENDOR CRITICAL PATH

Tier 1: Must Have BAAs (P0)

Cannot proceed without these BAAs

1. **Cloud Provider** (AWS/Azure/GCP)
 - Hosts all infrastructure
2. **LLM Provider** (OpenAI/Anthropic)
 - Receives PHI in prompts
3. **Vector Database** (Pinecone/Weaviate)
 - Stores ePHI embeddings
4. **Database Provider** (RDS/MongoDB)
 - Stores all PHI
5. **EHR Integration** (Epic/Cerner)
 - Exchanges PHI

Tier 2: BAA If PHI Present (P1)

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

Tier 3: Avoid (No BAA)

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

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
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□ 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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