

AI Scribe Build & Compliance Checklist

Run an ambient clinical-documentation feature through the four gates before you ship it. Engineering guidance, not legal advice — confirm specifics with counsel.

GATE 1 · CONTRACT (the BAA, plus the AI clause)

- Signed BAA on file with the scribe vendor before any audio is sent (45 CFR 164.502(e))
- BAA covers the exact tier/config you use — not just 'the vendor offers one'
- AI clause added: vendor may NOT train its general model on your patients' data
- Self-build? A BAA with EVERY vendor in the chain — the ASR API and the LLM both see PHI
- Public / consumer AI tiers blocked at the network — no transcript paste-ins

GATE 2 · PHI BOUNDARY (where the audio goes)

- Consult audio treated as PHI end to end — encrypted in transit and at rest
- Minimum necessary: keep only what the task needs; delete raw audio after the note is signed
- Recording consent captured; retention period defined and defensible (state-specific)
- Audit log records who opened audio, transcript, and note (45 CFR 164.312(b))
- Access controls limit transcripts/audio to the people who need them

RED FLAGS (stop before you ship)

- Anyone pasting a real transcript into a free, public chatbot — no BAA, possible training use
- A note auto-filed to the chart, or a clinician signing a stack without real review
- Speaker mix-ups left unchecked — the patient's words attributed to the clinician
- A scribe quietly suggesting a diagnosis to the patient — that crosses the FDA device line

GATE 3 · FDA LINE + GATE 4 · HUMAN REVIEW

- Scribe documents the visit; it does not diagnose or auto-decide (non-device, FDA CDS Jan 2026)
- Any suggestion (codes, care gaps) is reviewable by a clinician who can override it
- No note enters the chart until a clinician reviews, edits, and signs it
- A real review window is built into the schedule — not a few seconds between patients
- Draft state is visibly unsigned and excluded from the legal record until signed
- EHR write-back posts a DRAFT (FHIR DocumentReference); the clinician's signature finalizes

THE ONE-LINE RULE

An ambient scribe is three models in a row — speech recognition, speaker separation, and clinical summarization — that turn a consult into a draft note, and it is telehealth's highest-ROI AI feature because it gives clinicians back roughly an hour a day. But the consult audio is the most sensitive PHI you hold, so gate the feature in order: a signed BAA with a no-train clause, a PHI-boundary plan that keeps only what it must, the FDA documentation-versus-decision line, and a clinician who reviews and signs every note. The machine learning is a commodity you can buy; placing it correctly relative to the boundary, the device line, and the signature is the work that keeps a launch — and the clinicians using it — out of trouble.