AI Feature Map & Compliance-Gate Checklist

Run every AI feature you plan to add to a telemedicine product through the four gates below. Engineering guidance, not legal advice — confirm specifics with counsel.

THE SIX PLACES AI FITS (pick the features, then gate each one)

- ☐ Ambient scribe: listens to the consult, drafts the clinical note (mature, low risk)
- ☐ Transcription / captions: live captions for accessibility and the record (mature)
- ☐ Medical translation: cross-language consults — augments, rarely replaces, a human
- ☐ Triage / symptom intake: pre-visit routing — watch the FDA diagnosis line
- ☐ Visit summarization: provider note + plain-language after-visit summary
- ☐ RPM anomaly detection: trends and alerts on home-device data — watch alert fatigue

RED FLAGS (stop before you ship)

- ☐ Anyone pasting real patient data into a free, public chatbot — no BAA, possible training use
- ☐ PHI in logs, prompts, URLs, or error trackers shared with a non-BAA service
- ☐ A patient-facing chatbot stating a likely diagnosis — that crosses the FDA device line
- ☐ An AI output auto-filed to the record or sent to a patient with no human review

GATE 1 · CONTRACT + GATE 2 · PHI BOUNDARY

- ☐ Signed BAA on file with every vendor that creates, receives, or transmits PHI
- ☐ 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
- ☐ Model runs inside the boundary, OR data is de-identified before it leaves
- ☐ De-identification by Safe Harbor (18 identifiers) or Expert Determination (45 CFR 164.514)
- ☐ Encryption is assumed, not the finish line — encrypted-to-a-non-BAA-vendor is still a breach

GATE 3 · FDA LINE + GATE 4 · HUMAN REVIEW

- ☐ Feature supports a clinician's judgment; it does not diagnose the patient directly
- ☐ Clinician can independently review the basis of any recommendation (non-device CDS)
- ☐ No image/device-signal analysis producing a diagnostic output (that is a regulated device)
- ☐ Checked against FDA CDS guidance (Final, Jan 2026) — re-confirm version at launch
- ☐ A qualified person reviews and accepts every AI output before it counts
- ☐ Scribe note is signed; after-visit summary is approved; triage only suggests routing

THE ONE-LINE RULE

AI in telehealth is six features, not one switch — and every one of them sends patient data somewhere to be processed. So gate each feature in order: a signed BAA with the vendor, a PHI-boundary decision (keep the model inside or de-identify first), the FDA support-versus-diagnosis line, and a human who reviews every output. Documentation and transcription are mature and low-risk in 2026; triage and monitoring sit near the device line, so frame them as clinician support, never patient diagnosis. The technology is the easy part; placing it correctly relative to the PHI boundary and the device line is the work that keeps a launch out of trouble.