# Telemedicine Pilot & Rollout — Readiness Checklist



From a tested build to real patients. Tick each before you scale. Engineering guidance, not legal advice — confirm specifics with counsel.

## 1 · DESIGN THE PILOT (decide success before patient one)

- ☐ **Write success criteria first** — targets across access, effectiveness, experience, cost (NQF domains). A pilot with no criteria can't fail, so it can't teach.
- ☐ **Pick the hardest cohort** — older patients, poor networks, old devices. A pilot that works only on fast Wi-Fi has validated nothing.
- ☐ **Size it honestly** — to be ~95% sure of catching a 5%-of-visits problem, run ≥60 completed visits (0.95^n ≤ 0.05); ~300 for a 1% problem.
- ☐ **Name an owner + a feedback loop** — collect staff/patient feedback, change the product, show you did.

## 2 · THE LEGAL FORK — QI OR RESEARCH?

- ☐ **Decide intent, in writing** — improving care in YOUR setting = quality improvement; producing generalizable, publishable knowledge = research.
- ☐ **Research → IRB first** — human-subjects research (Common Rule, 45 CFR §46.102(l)) needs ethics-board review BEFORE you enroll a patient.
- ☐ **Near the line? Get it in writing** — ask the IRB for a determination; don't talk yourself into 'it's just QI'.

## 3 · PRE-PILOT COMPLIANCE GATE (no pilot holiday)

- ☐ **Full HIPAA applies day one** — confidentiality, integrity, availability of PHI (45 CFR §164.306(a)); risk analysis done (§164.308(a)(1)(ii)(A)).
- ☐ **BAAs signed before patient one** — every vendor touching PHI (video, cloud, analytics, crash tools) has a Business Associate Agreement. Binary.
- ☐ **Shrink the data, not the safeguards** — answer pilot questions with de-identified/aggregate data where you can; keep PHI in the production boundary.

## 4 · CLINICAL VALIDATION & THE FDA LINE

- ☐ **Plain video visit** — validation = the pilot: visits complete, clinicians can decide, outcomes no worse than in person.
- ☐ **Measures / scores / interprets data?** — FDA SaMD: clinical association → analytical validation → clinical validation, in order.
- ☐ **Decision support vs diagnosis** — software that drives a diagnosis may be a regulated device → formal V&V; (IEC 62304). Get a read BEFORE you build it.
- ☐ **Validation doesn't stop at launch** — monitor real-world performance; models and workflows drift.

## 5 · CLINICIAN ONBOARDING (where products die)

- ☐ **Recruit a clinical champion** — a respected peer who uses it early; peers adopt what trusted peers adopt, not what management mandates.
- ☐ **Train the real workflow** — where the visit fits between the patient before and after, incl. scheduling, documentation, billing.
- ☐ **Make support fast** — a clinician who hits a wall once with no help won't try a third time.

## 6 · PHASED ROLLOUT (rings, with a way back)

- ☐ **Expand in rings** — internal → pilot cohort → limited release → general availability. Widen only when the metrics hold.
- ☐ **Rollback plan per ring** — a tested way to fall back to the previous version or to in-person care. In telemedicine it's a safety control.
- ☐ **Confirm the path to payment** — billing/reimbursement works in the rings (Medicare flexibilities currently through Dec 31, 2027 — re-verify).
- ☐ **Check cross-state licensing** — as rings add patients in new states, the clinician must be licensed where the patient is.

## THE ONE QUESTION BEFORE YOU SCALE

Ask: "Did this pilot run on the patients, networks, and devices that scale will actually bring — and did we set, in advance, what would make it fail?" If the pilot ran with eager staff on good Wi-Fi with new phones and no pre-set criteria, it was designed to succeed, and a pilot that can't fail has told you nothing. The entire value of a pilot is its power to surface problems while they are still cheap — while they reach ten patients, not ten thousand. Treat a problem found in the pilot as the pilot working. Then roll out in rings, keep the compliance and clinical bars at every ring, and keep a rehearsed way back, so the worst day in production is a controlled rollback instead of a population-wide incident.