Chronic Care & RPM — Program Readiness Checklist

Run this on a chronic care management (CCM) or remote patient monitoring (RPM) build before launch. Engineering guidance, not legal advice — confirm specifics with counsel.

PROGRAM & BILLING — THE CODES ARE THE SPEC

- ☐ **16-day adherence counter, per patient.** Code 99454 needs device data on at least 16 of 30 days. The product counts adherence days live, shows a '12 of 16' indicator, and nudges patients who fall behind. For 2-15 days, bill the new 2026 code 99445 instead — never both.
- ☐ **Monthly live-interaction log.** Treatment-management codes 99457 / 99470 require one real two-way conversation with the patient or caregiver each month, timestamped. No logged conversation, no billable management time.
- ☐ **Time tracking that survives an audit.** Every billable minute is attributed to a person, a patient, and an activity. CCM thresholds (20 min for 99490, 30 min personally for 99491) and RPM 20-min increments (99458) are proven from the log, not estimated.
- ☐ **Consent captured at enrollment.** CCM and RPM both require recorded consent, including the cost-sharing disclosure (~20% Part B coinsurance; ~$8/month CCM copay). Store it where an auditor can find it.
- ☐ **One-practitioner-per-month lock (CCM).** Only one practice can bill CCM for a patient in a given month. Enforce it in the data model so a double-enrollment cannot generate a claim and a clawback.
- ☐ **Established-patient and 2+ chronic conditions.** RPM requires an established patient relationship; CCM requires two or more chronic conditions expected to last 12+ months, with a comprehensive care plan in the record.

DEVICE, DATA & COMPLIANCE

- ☐ **FDA-defined device, automatic transmission.** RPM data must come off a device that meets the FDA medical-device definition and transmit on its own. Manually typed readings are denied. Prefer cellular devices for an older population — no phone, no app, better 16-day adherence.
- ☐ **BAA across the whole stream.** The device maker's cloud, the cellular-connectivity provider, and your platform each touch PHI and each need a signed Business Associate Agreement. Encrypted is necessary, not the same as compliant.
- ☐ **Normalize to FHIR; write back to the EHR.** Terminate device variety at an ingestion layer, map each reading to a FHIR Observation tied to a Device and Patient, and surface it in the chart and the care dashboard.
- ☐ **Encryption, access control, audit on the stream.** Encrypt in transit and at rest (45 CFR 164.312); log which staff member viewed which patient's stream and when. Continuous data makes the audit trail larger, not optional.
- ☐ **De-identify before analytics.** Population trends, quality metrics, and model training need readings either inside the boundary under a BAA or properly de-identified (45 CFR 164.514(b)). A raw, patient-tagged stream into a no-BAA analytics tool is a violation.
- ☐ **Measurement bias and a named triage owner.** Know sensor limits (pulse oximetry overestimates in darker skin; Section 1557 45 CFR 92.210). Use personalized baselines, triage alerts by severity, and give every monitored patient an owner and an escalation path.

THE ONE TEST BEFORE LAUNCH

Enroll one patient and prove the hard parts work end to end: a reading comes off an FDA-defined device and transmits automatically (no manual entry); the platform counts adherence days against the 16-day rule and nudges a patient who is behind; a monthly live conversation is logged and tied to the treatment-management code; consent with the cost-sharing disclosure is on file; the device vendor and the connectivity provider both have a signed BAA; and a dangerous reading reaches a named owner with an escalation path. If any of those fails, the product is not ready — the failure is either a denied claim or an unwatched patient.