Specialty Visual Consults — Readiness Checklist

Run this on a teledermatology, digital wound-care, or teleophthalmology build before launch. Engineering guidance, not legal advice — confirm specifics with counsel.

CAPTURE & COMPLIANCE

- ☐ **Capture meets a published bar.** Diagnostic-grade resolution and controlled lighting (the AAD recommends a minimum 800x600 for skin); a size reference and a color reference in the frame so two photos weeks apart are comparable.
- ☐ **Camera paired to the algorithm.** If a cleared AI reads the image, use only the camera it was cleared with — FDA-cleared retinal systems are validated with specific named cameras. Hardware and software are cleared together; the camera is not a swappable accessory.
- ☐ **Images encrypted in transit and at rest.** Uploads over TLS; stored images encrypted (45 CFR §164.312(a)(2)(iv), addressable — implement it). Encrypted is not the same as compliant.
- ☐ **BAA with every image handler.** A signed Business Associate Agreement with the cloud image store, any AI vendor that reads the image, and the EHR you push the report into. No un-BAA'd bucket, no consumer photo SDK.
- ☐ **Treat every image as identifiable PHI.** A face, an iris, a tattoo, and embedded EXIF metadata each identify the patient; HIPAA Safe Harbor names full-face photos as identifiers (45 CFR §164.514). 'We'll anonymize for analytics' is usually wishful.
- ☐ **DICOM where the hospital needs it.** Ophthalmology imaging is DICOM-native and dermatology is migrating (DICOM WG-19). Plan for standards-based exchange, not just JPEGs in a bucket.

THE DEVICE LINE & BILLING

- ☐ **Run the display-vs-interpret test.** If software only moves, stores, or shows the image, it is usually a non-device (MDDS, 21st Century Cures Act §3060). If it interprets the image to output a diagnostic or screening result, it is usually a regulated device.
- ☐ **No accidental medical device.** A feature that scores a mole's risk or auto-measures a wound and shows a result may be Software as a Medical Device needing FDA authorization (De Novo / 510(k)). Decide this deliberately, before you build it.
- ☐ **Automation-bias check.** Per FDA Clinical Decision Support guidance (final 2022-09-28), software that hands a clinician a directive they can't independently review looks like a device. Keep a non-device feature reviewable.
- ☐ **Who interprets sets the code.** In retinal imaging: staff read = 92227, physician read = 92228, autonomous AI = 92229. The interpreter sets both the FDA class and the CPT code.
- ☐ **Store-and-forward reimbursement mapped.** Asynchronous patient-initiated visits use e-visit codes 99421-99423; remote image evaluation uses G2010. Rules are jurisdictional and dated — confirm current parity for your payers and states.
- ☐ **FDA pathway owned, if applicable.** If you are building a device, the clearance program (and its timeline and cost) belongs in the plan from day one — not discovered after launch.

THE ONE TEST BEFORE LAUNCH

Open one consult and prove the hard parts: the captured image is good enough for a specialist or a cleared algorithm to make the call, with a scale and color reference in the frame; the image is encrypted in transit and at rest and every handler that can see it has a signed BAA; you can state in one sentence whether your software displays the image or interprets it — and if it interprets, the FDA pathway is in the plan; and the billing code matches who actually does the reading. If any of those is unclear, the product is not ready — in these specialties the failure is a missed diagnosis, an exposed face, or an unauthorized medical device.