Palo Alto Health Labs

AI Scribe and Clinical AI Vendor Evaluation Checklist for Practices

Not legal advice. Not a compliance certification.

Evaluate a specific product, version and intended use—not “AI” as a single category. This is a proposed procurement and pilot worksheet, not a clinical-validation protocol or regulatory determination.

Vendor/legal entity: _____ Product/version/configuration: _____
Proposed users/settings: _____ Practice decision owner: _____
Clinical reviewer: _____ Technical/security reviewer: _____
Evaluation date: _____ Contract/scope reviewer: _____

For each item mark Evidence reviewed / Open / Not applicable with reason. Record source/date, reviewer and next action. Do not total a score or equate a polished demo with readiness.

1. Intended use and boundaries

☐ Describe whether the function captures audio, transcribes, summarizes, drafts documentation, suggests codes, recommends clinical actions or does something else.

☐ Identify intended population, specialty, setting, languages and excluded uses.

☐ State what action a user may take from the output and what remains outside scope.

☐ Ask for the vendor's function-specific regulatory rationale and supporting documentation; route it to an appropriate reviewer rather than accepting a blanket “FDA approved” badge.

FDA explains that software products can contain different functions with different regulatory treatment; CDS guidance alone is not sufficient to determine every function's status. This checklist does not classify any scribe or vendor. [3]

Evidence / open issues / owner: _____

2. Workflow and human review

☐ Identify who starts/stops capture and how patients/staff know capture is active.

☐ Obtain review of applicable recording permission, notice and consent requirements for the actual settings/jurisdictions; this checklist supplies no legal conclusion.

☐ Specify who compares drafts with the encounter/source, corrects them and accepts them before filing or action.

☐ Demonstrate how draft status, authorship, corrections and missing/uncertain information appear.

☐ Rehearse refusal of capture, interrupted encounters, multiple speakers and fallback documentation without the tool.

Proposed safeguards require clinical review; human acceptance alone does not establish clinical validity or compliance.

Evidence / open issues / owner: _____

3. Clinical validity and failure cases

☐ Request evidence tied to the exact task, population, product/model version and operating conditions—not only broad model benchmarks.

☐ Ask how reference labels, reviewers, disagreement and clinically important error definitions were handled; distinguish vendor-reported results from independent evidence.

☐ Design a locally approved evaluation beginning with synthetic examples; any real-data pilot needs separate authorization and safeguards.

☐ Test proposed cases: omitted negation, wrong speaker/patient, medication/dose/unit errors, fabricated facts, copied history, uncertain audio, language variation, missing context and contradictory records.

☐ Name a clinical reviewer to define acceptance and stopping criteria before testing.

☐ Document correction burden and whether reviewers can reliably detect important errors in the actual workflow.

These are recommended evaluation prompts, not claims that every product has these failures or that this worksheet is a validated study design.

Evidence / open issues / owner: _____

4. Integration and authority

☐ Confirm exact EHR/environment support, resource/field mappings and read versus write permissions.

☐ Test patient/encounter binding, context switches, partial responses, timeouts and duplicate filing prevention.

☐ Require a documented correction/reconciliation and downtime workflow.

☐ Assign who approves model, template, integration and version changes and when reevaluation occurs.

Evidence / open issues / owner: _____

5. Data uses, vendor scope and contracts

☐ Map raw audio, transcript, prompt, output, identifiers, telemetry, support access, caches, backups and subprocessors.

☐ Ask about training, improvement, human review and secondary uses; confirm actual contract terms and settings rather than assuming an opt-out.

☐ Record retention/deletion/export, access roles, security controls and incident escalation.

☐ Where required, establish signed BAA coverage for the precise vendor/service arrangement, exclusions and subcontractor handling. A BAA alone is not sufficient. [1][2]

☐ Review responsibilities for output, support, changes, termination and unresolved defects without inventing certification requirements.

Evidence / open issues / owner: _____

6. Decision and follow-up

Outcome: More evidence / Synthetic-data evaluation / Seek approved pilot / Decline / Pause
Rationale and unresolved boundaries: _____
Clinical acceptance reviewer / reference: _____

Technical/contract reviewer / reference: _____
Next action / owner / date: _____
Reassessment trigger/version change: _____

Do not treat procurement approval, a BAA or a local demo as clinical validation for new uses.

Sources and editorial appendix

Official sources opened/read 2026-11-07 PST:

[1] HHS cloud guidance <https://www.hhs.gov/hipaa/for-professionals/special-topics/health-information-technology/cloud-computing/index.html>.
[2] HHS Security Rule summary <https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html>.
[3] FDA CDS FAQs <https://www.fda.gov/medical-devices/software-medical-device-samd/clinical-decision-support-software-frequently-asked-questions-faqs>, especially multiple-function and regulatory-scope discussion.

Limitations: no vendor evidence, device clearance/approval record, recording-consent law, local EHR configuration or clinical performance was evaluated. FDA FAQ is context, not a product-specific legal opinion. Mike/clinical reviewer must review failure cases and human-review language; counsel must review intended-use/regulatory and recording requirements. No blanket HIPAA, FDA or certification claims should be introduced.

Limits

No PAHL capability, certification, outcome or delivery promise is asserted.

Not legal advice.

No booking URL, availability or free-call deliverables have been verified.