VALUE ANALYSIS COMMITTEE

Submission Packet

Pre-filled committee submission for ARKA's real-time clinical decision-support and order-monitoring platform — vendor identity, regulatory posture, clinical evidence, financial impact, and implementation, prepared for value-analysis review.

FDA Non-Device CDS · §520(o)(1)(E) | HIPAA BAA ready | CMS-0057-F aligned | SOC 2 (in progress) | Supports, not replaces clinical judgment

DOCUMENT	VERSION	GENERATED	CLASSIFICATION
VAC Submission Packet	1.0	July 6, 2026	Confidential

VAC SUBMISSION PACKET · V1.0

Contents

ARKA is real-time order monitoring software: it watches imaging orders at the moment of entry via CDS Hooks and delivers almost-instantaneous, evidence-cited appropriateness suggestions (typically under 800 ms) — in-flow, without a separate screen.

ABOUT THIS PACKET

Figures are drawn from ARKA's canonical site modules — pricing, evidence, security, and implementation — and stated with honest status. Certifications marked “in progress” are not represented as complete. ARKA supports, and does not replace, clinical judgment (FDA Non-Device CDS §520(o)(1)(E)).

A Vendor & Product Identification

LEGAL NAME **ARKA Health, Inc.**	WEBSITE https://www.getarka.health
PRODUCT ARKA platform — real-time order monitoring software (ARKA-CLIN Non-Device CDS; ARKA-INS administrative support)	
CATEGORY Real-time clinical decision support and order monitoring (imaging appropriateness) + prior-authorization workflow layer — no hardware, no implant, no capital equipment	
CONTACTS arrihantk@getarka.health Security: security@getarka.health Privacy: privacy@getarka.health	FOUNDED · TEAM · CAPITALIZATION See Company & Financial Stability Brief (/company/brief) — TG-5 gated facts stated plainly.

B Product Description & Clinical Indication

Clinical register — intended use (verbatim from **/trust**, ARKA-CLIN, Document 03):

> *ARKA-CLIN is intended for licensed health care professionals to support selection of clinically appropriate diagnostic imaging using structured clinical data. It presents ranked, evidence-cited imaging options drawn from published clinical guidelines and peer-reviewed literature, with the basis available for independent review. It does not acquire, process, or analyze medical images or physiological signals; does not provide time-critical alerts or triage; and does not place, cancel, or block orders.*

Mechanism. Rules-first, guideline-anchored engine — every recommendation is anchored to a published guideline; if no guideline-anchored rule fires, ARKA-CLIN returns no card. Optional XGBoost refinement with SHAP is secondary and labeled; the system falls back to rules-only output when the model is unavailable.

Real-time monitoring. ARKA is real-time order monitoring software: it watches imaging orders at the moment of entry via CDS Hooks and delivers almost-instantaneous, evidence-cited appropriateness suggestions (typically under 800 ms) — in-flow, without a separate screen.

EXPLICIT NEGATIVE SCOPE

Does not acquire, process, or analyze medical images or physiological signals; no time-critical alerts or triage; does not place, cancel, or block orders.

C Regulatory & Compliance Status

- HIPAA BAA ready — In force
- SOC 2 Type II in progress — In progress
- Non-Device CDS — In force
- CMS-0057-F aligned — In force
- HIPAA — Privacy, Security & Breach Notification Rules — Program in force
- SOC 2 — Security, Availability, Confidentiality — In progress
- HITRUST e1 — Essentials, 1-Year Validated — Roadmap active

- **HIPAA:** Program in force — full privacy and security policy suite adopted; BAA ready for execution.
- **SOC 2:** Readiness assessment complete against the 2017 Trust Services Criteria (2022 points of focus). Type I examination targeted December 2026; Type II report mid-2027 — in progress; ARKA does not claim attestation before the auditor's report is issued.
- **HITRUST e1:** Roadmap active — ARKA is not HITRUST certified and will not use the seal until validated assessment is issued.
- **FDA:** Non-Device CDS designed to §520(o)(1)(E) four criteria per FDA's January 2026 revised final CDS guidance.
- **Q-Sub:** Pre-Submission (Q-Sub) package prepared (v1.0, June 9, 2026); filing pending completion of pre-filing gates.
- **CMS AUC program:** CMS AUC program paused effective January 1, 2024; 42 CFR §414.94 rescinded. ARKA operates on its independent AIIE + peer-reviewed-literature standard; no CDSM consultation is required on claims while the program is paused.
- ARKA's AIIE engine is designed to operate independently of any single criteria licensor — drawing on peer-reviewed clinical literature, CMS Appropriate Use Criteria Program standards (PAMA §218(b)), and first-party machine-learning validation.

CMS-0057-F — HONEST STATUS PER REQUIREMENT

REQUIREMENT	STATUS
Patient Access API	In progress
Provider Access API	In progress
Prior Authorization API (Da Vinci PAS)	Implemented (sandbox)
CRD — coverage requirements discovery	Implemented (sandbox)
DTR — documentation templates & rules	Implemented (sandbox)
Denial reason transparency	Implemented (sandbox)
PA decision timeframes (72h expedited / 7 calendar days standard, from Jan 1, 2026)	Implemented (sandbox)
Payer-to-Payer API	N/A for our scope

ONC HTI-1: ARKA supplies predictive-DSI source-attribute documentation (31 attributes) to support the hospital's certified-EHR transparency obligations (45 CFR 170.315(b)(11)).

D Clinical Evidence Summary

Evidence ladder — tier definitions and claim boundaries, with honest maturity status.

Tier 1 — Synthetic validation Published

Model performance measured against a synthetic, appropriateness-aligned cohort (~5,000 cases; RAND/UCLA 1–9 scale semantics derived from peer-reviewed literature).

Tier 2 — Retrospective evaluation on real-world data In progress

ARKA scored de-identified historical imaging orders provided by a partner health system and compared output against what actually happened (payer outcomes, documentation completeness).

Tier 3 — Prospective pilot (IRB-reviewed analysis) Planned

Live in-workflow use with a pre-registered analysis plan; the only tier that can claim operational before/after deltas.

Modeled economics Published

Projections built from published industry inputs (CAQH, KFF, MGMA, AMA) or from Tier-1/Tier-2 measurements, scaled.

Tier 1 — published synthetic result

~74% three-class accuracy, N≈5,000 synthetic cohort. Real-world clinical or operational performance is not claimed at this tier.

Tier 2 — Stormont Vail retrospective evaluation

Retrospective scoring replayed historical orders through the same real-time monitoring pipeline used in production — measuring how quickly ARKA would have surfaced suggestions and what it would have flagged before submission.

METRIC	RESULT	NOTE
Historical orders scored	2,310	De-identified advanced-imaging orders from a 12-week extract window
Median scoring latency	<800ms	in simulated chart

MODELED

METRIC	PROJECTION	ASSUMPTION
Projected denial-rate reduction if flags are actioned	Pending computed value	Assumes documentation gaps closed at order entry convert stated% of flagged denials to clean claims — the assumption the prospective pilot tests.
Projected annual benefit at full deployment	~$3.0M modeled annual benefit	Scaling the observed 13.3-point denial-rate reduction across ~31,000 annual advanced-imaging orders ≈ 4,120 denials prevented/yr. At a ~$1,180 blended value and ~55% historically never reworked, that is ≈$2.7M in recovered revenue, plus ≈$0.19M in prior-auth admin labor and ≈$0.10M in rework labor avoided. Modeled, conservative; not a guarantee of outcomes.

Tier 3 — prospective study

ARKA-PROSPECT-01 • Protocol drafted

Protocol drafted — design details available upon request.

Current validation limitation, disclosed proactively: ARKA's published accuracy figure (~74% three-class) is measured on a synthetic cohort and is not a clinical-performance claim. Real-world retrospective evaluation is in progress at one site; prospective operational outcomes are the objective of ARKA-PROSPECT-01. We disclose this because committees should not discover limitations after deployment.

E Financial Impact & Pricing

TIER	PRICE	SCOPE
Starter	$0.35 / order	ARKA-CLIN only
Pro	$0.45 PMPM	ARKA-CLIN + ARKA-INS
Enterprise	Custom contract · Min $500K ARR	Full platform incl. ARKA-ED + ARKA-RURAL

- **Pilot economics:** Priced to signal seriousness, not to profit — a fixed pilot fee credited toward the enterprise contract. Starter CLIN pilots begin at $0.35 per order; see pricing for Pro and Enterprise paths.
- **Guarantee:** If your pilot doesn't hit the agreed success threshold, month 1 of production is free.
- **Modeled ROI:** *Modeled* — see ROI narrative.
- Because ARKA monitors every order in real time and surfaces suggestions before submission, documentation gaps and denial-risk flags are actionable at the point of order — not after a payer denial.
- The 90-day pilot is priced to fit a departmental operating budget; no capital request required.

Three budget pathways

Pathway 1 — Departmental operating budget (default)

90-day pilot at a fixed fee sized for a single service line's operating authority — no capital committee required.

Pathway 2 — Regulatory / compliance program alignment

The Medicare Promoting Interoperability program adds an 'Electronic Prior Authorization' attestation measure for eligible hospitals and CAHs beginning with the CY 2027 EHR reporting period (finalized in CMS-0057-F). Payer Prior Authorization APIs go live January 1, 2027; payer decision clocks (72h expedited / 7 days standard) and specific-denial-reason requirements begin in 2026. Hospitals are budgeting readiness work for that transition now; ARKA's pilot fits those readiness lines because the same integration exercises CRD/DTR/PAS workflows end-to-end.

Pathway 3 — Phased / deferred structure

Split pilot fees across a fiscal-year boundary; align enterprise ramp pricing to value milestones at quarterly business reviews.

F Implementation & Training

Go-live delivers continuous, in-workflow order monitoring: clinicians receive almost-instantaneous suggestions at order entry; shadow mode measures latency and alert burden before any production enforcement.

PHASE	WINDOW	ARKA	YOU PROVIDE
Phase 0 — Paperwork	Week 0	Execute MSA and BAA, share the 21-document security package from our Trust Center, provision sandbox credentials, and seed your security questionnaire responses from the published controls on /security.	Procurement and security reviewers to execute agreements, complete the vendor questionnaire, and approve sandbox access for the integration team.
Phase 1 — Connect	Weeks 1–2	Provide CDS Hooks discovery URL, SMART on FHIR launch parameters, and registration checklists. ARKA consumes structured FHIR order-select context from the EHR prefetch bundle — no image pixels, no bulk PHI export.	Your EHR/integration team registers ARKA as a CDS Hooks service and SMART on FHIR app in non-production — designed for Epic, Oracle Health (Cerner), and athenahealth after customer-specific validation. Typical lift: one analyst, light ARKA support.
Phase 2 — Configure	Weeks 2–4	Map service lines and payer mix, narrow pilot scope to one department and one payer, tune auto-clear thresholds toward 35–40%, and align card copy with our CDS Card Language Style Guide (supportive, non-coercive, evidence-first).	Clinical and revenue-cycle sponsors to confirm pilot boundaries, approve threshold targets, and sign off on in-flow card wording before shadow mode.
Phase 3 — Validate	Weeks 4–6	Run shadow mode alongside live traffic, publish validation metrics and drill-down rows, and complete conformance checks against CDS Hooks and Da Vinci CRD expectations.	Clinical champion reviews shadow cards against local practice patterns, logs sign-off, and confirms the pilot KPI baseline before production enablement.
Phase 4 — Go live	Weeks 6–8	Enable ARKA in production for the agreed pilot scope, monitor API latency and card delivery, and report ROI and utilization metrics through the observability dashboards.	Change-control approval for production CDS registration, a named on-call contact for the first two weeks, weekly readouts with your champion and rev-cycle lead, and confirmation that the rollback runbook is delivered and walked through before production enablement.

INTERNAL HOSPITAL RESOURCES

ROLE	EFFORT	RESPONSIBILITY
EHR integration analyst	~20–40 hours (weeks 1–4)	Registers CDS Hooks services and the SMART app in non-prod and production, validates prefetch scopes, and attends one ARKA working session per week during connect and configure.
Security / privacy reviewer	~8–12 hours (week 0)	Reviews the BAA, security questionnaire, and data-flow statement; approves sandbox and production network paths with your CISO or delegate.
Clinical champion (CMIO or service-line lead)	~4–8 hours (weeks 2–6)	Defines pilot scope, approves card copy and auto-clear thresholds, reviews shadow-mode output, and signs the clinical go-live log.
Revenue-cycle / denials lead (optional but recommended)	~2–4 hours (weeks 4–8)	Supplies baseline denial and clean-claim metrics, validates KPI definitions, and co-owns the weekly pilot readout with finance.

Risk controls & rollback

Rollback protocol — ≤2 business hours, zero EHR rebuild

ARKA attaches via CDS Hooks service registration and a SMART on FHIR app record. Full deactivation = deregistering those entries in EHR configuration — a config change by your analyst with our engineer on the line, not a build project. No order data, order sets, or clinical content in your EHR is modified by ARKA, so there is nothing to rebuild after rollback. Rollback can be scoped (one department, one hook) or total. We commit to a documented rollback runbook delivered before go-live and a ≤2-business-hour assisted rollback SLA.

Failure behavior — fail-open by design

If ARKA is unreachable or slow, the EHR proceeds exactly as it did before ARKA existed: no card renders, no order is delayed or blocked. ARKA cannot place, cancel, modify, or hold orders (see /trust intended use). A rules-only fallback also covers ML-service outages: guideline-anchored cards continue without the optional model refinement.

Go-live service levels

Availability targets, incident response tiers, and scoring latency commitments are shared during contracting and documented in the MSA SLA exhibit. During the first two production weeks: daily check-ins and a named on-call engineer.

Named implementation engineer

Every deployment is assigned a named ARKA implementation engineer — one accountable human from Phase 1 through 90 days post-go-live, present in weekly readouts (also the escalation point in the SLA).

Alert-fatigue guardrails

ARKA is silent unless a guideline fires (zero-click baseline measured on the pilot scorecard); card volume thresholds are reviewed weekly during the pilot; any card class exceeding agreed volume or override thresholds is tuned or retired via the shadow-mode review loop with your clinical champion (Phase 3). Override/feedback rates are a first-class KPI on /outcomes, not an afterthought.

Change management & training

Training is role-based and short by design (the tool adds no screens): 15-minute ordering-clinician orientation (what a card is, how to see the reasoning, how to give feedback), 45-minute session for champions/UM, plus quick-reference sheet. Communication templates for go-live announcements are provided. Model or rule-library changes follow the documented change-control process in the Q-Sub package and are release-noted to your team.

G Support & References

- **Support model:** Support hours, channels, and incident tiers are documented in the MSA SLA exhibit — shared during contracting. First-two-weeks production coverage includes daily check-ins and a named on-call engineer. Real-time order monitoring continues in production — suggestions remain almost instantaneous at order entry.
- **Named implementation engineer:** Every deployment is assigned a named ARKA implementation engineer — one accountable human from Phase 1 through 90 days post-go-live, present in weekly readouts (also the escalation point in the SLA).
- **Reference policy:** Named references are available to qualified prospects under mutual courtesy limits (≤2 calls/month per reference) via the access request form. See References & evidence.
- A physician-champion letter template is provided (Champion Toolkit) — ARKA pre-formats the letter so your sponsoring physician's submission is a 20-minute task, not a writing project.
- **Post-go-live governance:** After pilot go-live, success is governed on a defined cadence (weekly → monthly → quarterly QBR) with shared accountability — see outcomes — success governance. QBR agenda template: `docs/customer-success/QBR_AGENDA_TEMPLATE.md` (vendor portal).

H Attachments Checklist

Full diligence index with live template status: ARKA Vendor Portal (/procurement).

#	DOCUMENT	AVAILABILITY
1	**ARKA Vendor Portal (diligence hub)** /procurement · Single link for contracting teams — all diligence artifacts with honest availability status.	Available
2	**One-page overview** /overview · PDF: /briefs3/ARKA One Page Overview.pdf · also at /resources	Available
3	**Evidence ladder** /evidence/methodology · Tier definitions and claim boundaries	Available
4	**Case study / evaluation** /case-studies/stormont-vail-health · Stormont Vail Health retrospective evaluation	Available
5	**Model card** /docs/model-card · Shared under NDA	Under NDA
6	**Model Limitations & Oversight** /docs/model-limitations · Public committee brief — 74% disclosure, failure modes, oversight loop	Available
7	**AI Governance Package** /governance/ai · RUAIH-mapped submission — Joint Commission/CHAI seven elements with HTI-1, NIST, and FDA/CMS crosswalks	Available
8	**Security & compliance package** /security · 27 controlled documents under NDA (6 series indexed on /security)	Under NDA
9	**Data-flow & PHI statement** /data-flow · Hop diagram and PHI handling statement	Available
10	**Subprocessor list** /security/subprocessors · PHI-relevant subprocessors in the production serving path; 30-day change notification	Available
11	**BAA template (ARKA-LGL-001)** Attorney-drafted template — available on request; countersigned within 2 business days	On request
12	**MSA + DPA + AUP + Cybersecurity addendum** In legal preparation — available upon request with committed delivery in the MSA timeline	In preparation
13	**Insurance certificates (E&O / cyber)** Available on request	On request
14	**CMS-0057-F matrix** /compliance/cms-0057-f-matrix · Requirement-by-requirement capability mapping	Available
15	**Hospital-side CMS-0057-F brief** /compliance/cms-0057-f-hospital-brief · Provider-side impact brief — PI attestation, payer clocks, Da Vinci readiness	Available
16	**Implementation & rollback plan** /implementation · Phases, staffing, and documented rollback commitments	Available
17	**Pilot protocol + success contract** /pilot · Co-signed KPI scorecard and Pilot-to-Production guarantee	Available
18	**Company & financial stability brief** /company/brief · Print-ready stability brief — TG-5 gated facts stated plainly	Available

I Signature Blocks

PHYSICIAN CHAMPION ATTESTATION

"I have reviewed this submission and sponsor its evaluation by the committee."

Name

Title / Department

Signature

Date

VAC DECISION

- [ ] Approve
- [ ] Approve with conditions
- [ ] Defer
- [ ] Decline

Conditions (if applicable)

Next review date

Committee chair signature / date

STANDARD DISCLAIMER

Supports, not replaces clinical judgment — FDA Non-Device CDS §520(o)(1)(E). ARKA provides clinical decision support for licensed health care professionals; recommendations are advisory and require independent clinical judgment. **Synthetic data only — no PHI.**