LIFELINE MEDICAL TECHNOLOGIES

Precision Analgesia

The Active Safety Net for Inpatient Opioid Prescribing

A SMART on FHIR Clinical Decision Support engine that intercepts dangerous opioid orders *before* they reach the patient — designed to embed silently inside Epic and Cerner.

🏥 ENTERPRISE B2B SAAS | 🔬 FDA NON-DEVICE CDS EXEMPT | 💊 OPIOID SAFETY

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THE INPATIENT OPIOID BLIND SPOT

Hospitals are writing opioid orders without a safety net.

$78.5B

Annual U.S. economic burden of prescription opioid misuse, abuse, and dependence

Florence et al., Medical Care 2016

$303M

Single "Failure to Monitor" verdict (Asante Rogue Regional). Malpractice is now a nine-figure systemic threat.

Oregon Court of Appeals, 2023

46%

Floor patients experience opioid-induced respiratory depression. Manual nursing checks miss the vast majority.

PRODIGY Trial, Anesthesia & Analgesia (2020)

⚡ Alert Fatigue Is the Norm

Epic's native drug-safety warnings are dismissed **70–90% of the time (JAMIA)**. Clinicians have been trained to click past them. The system meant to protect patients has been optimized away.

💰 Settlement Abatement Funds — Eligible Use

Exhibit E of the National Opioid Settlement **explicitly lists point-of-care decision support** as an approved abatement use. Hospitals can apply for funding through state and county abatement programs.

WHY EXISTING TOOLS FAIL

The difference between reactive and proactive.

STATUS QUO

The Passive Calculator

- ✗ Doctor must consciously *remember* to open MDCalc or a calculator app
- ✗ Manually types in creatinine, weight, opioid doses — 45 seconds of friction
- ✗ Used only 5% of the time. Used in the cafeteria, not at the bedside.
- ✗ Boolean alerts ("MME > 90") dismissed in under 1 second
- ✗ No pharmacogenomics, cross-tolerance, or organ-specific gating

RESULT

Optional. Ignored. Liability.

→ vs →

PRECISION ANALGESIA

The Active Safety Net

- ✓ Silently monitors CPOE in the background via CDS Hooks
- ✓ Auto-pulls weight, labs, meds from FHIR — **zero manual entry**
- ✓ Intercepts dangerous orders *at the moment of signing*
- ✓ Returns specific, actionable guidance (not just "warning")
- ✓ CYP2D6 pharmacogenomics, OIRD scoring, renal/hepatic gating

RESULT

Automatic. Specific. Defensible.

HOW IT WORKS

A three-layer engine embedded in every opioid order.

LAYER 1 — BUILT

FHIR Ingestion

Patient context auto-loads via SMART on FHIR OAuth. Pulls age, weight, creatinine, active meds, allergies, genotype panel. **Zero manual entry.**

`R4 Patient` `Observation` `MedicationRequest`

LAYER 2 — BUILT

Clinical Pipeline

10 deterministic safety rules plus OIRD risk scoring, MME thresholds, pharmacogenomic guidance, and CDC naloxone prompts — all in <100ms.

`CDS Hooks` `PRODIGY` `CDC 2022`

LAYER 3 — SCAFFOLDED

FHIR Write-Back

1-click "Draft Order" injects safe alternative into Epic's CPOE cart. "Export to Chart" writes a billable consult note as a DocumentReference.

`MedicationRequest POST` `DocumentReference`

The Traceability Ledger — Our FDA Criterion 4 Shield

Every recommendation shows the exact formula, conversion factor, and guideline citation. The clinician can independently verify the math. This is legally defensible — not a black box.

FDA NON-DEVICE CDS

CLINICAL MODULES

Six tools. One workflow. Zero new logins.

Risk Assessment

OME/MME calculator, OIRD risk tier (PRODIGY-aligned), organ dose gating, naloxone prompt at ≥50 MME, manual data override form.

Opioid Tapering

CDC 2022 taper schedule generator. 10%/2-week protocol. One-click copy to EHR note.

OUD Consult

BUPE/methadone/naltrexone protocols. COWS, DSM-5, aberrant behavior screening. Auto-structured consult note.

Patch Conversion

Transdermal fentanyl/buprenorphine calculators with organ-adjusted dosing. Prevents the most common ICU conversion error.

Screening Suite

DAST-10, ASSIST, ORT with sex-adjusted scoring. Reads FHIR nursing flowsheets before prompting manual entry.

IV Infusion

PCA 1-hr/4-hr limit calculator. Continuous drip converter with renal-adjusted dosing. Prevents common ICU programming errors.

Manual Override Form — "Dirty Data Defense"
Clinicians correct/supplement FHIR data in real-time. 6 sections, EHR/Manual/Missing badges.

Copy-to-Note Workflow
All outputs copy as structured clinical text. Paste into Epic note. Citrix/VDI compatible.

REGULATORY & SECURITY MOATS

We bypassed the two graveyards before we started building.

THE FDA MOAT

Non-Device CDS Exemption

FDA's January 2026 guidance created a "Non-Device CDS" exemption for deterministic rules a clinician can independently verify. Our Traceability Ledger satisfies **Criterion 4** — engineered from day one.

Saves ~$2M + 2 Years
vs. 510(k) SaMD clearance required for AI/ML competitors

THE CISO MOAT

Zero-PHI Architecture

All calculations happen in-memory, discarded after the HTTP response. **No database. No PHI at rest. No HIPAA BAA complexity.** Every hospital CISO's nightmare — a data breach — is architecturally impossible.

Ships past security review in weeks, not years

THE INTEGRATION MOAT

SMART on FHIR + CDS Hooks

We embed natively via Epic's published APIs. We never ask hospitals to change their workflows. Once a validated clinical system is integrated, hospital IT will never unwind it.

THE FUNDING MOAT

Settlement-Funded Sales

Point-of-care CDS is an **Exhibit E eligible use** of National Opioid Settlement abatement funds. Qualifying hospitals can pay with settlement money — easing the capital budget conversation.

TOTAL ADDRESSABLE MARKET

A massive, underserved acute care opportunity.

TAM
$6.8B
U.S. hospital CDS / patient safety software market (2026)

SAM
$1.4B
Inpatient opioid safety & analgesic stewardship software segment

SOM (YEAR 3)
$87M
350 hospital systems × $250K ARR — conservative 6% share

Addressable Hospital Universe

Total U.S. acute care hospitals	6,090
Epic-affiliated hospitals	~2,800
Hospitals with opioid settlement exposure	~4,100
Hospitals with active abatement funds	~1,200

Why Now — Four Simultaneous Tailwinds

- FDA Jan 2026 guidance created a clear non-device exemption path
- Settlement abatement funds (Exhibit E eligible use) defuse budget objections
- Epic App Orchard actively recruits SMART on FHIR CDS partners
- CMS opioid quality metrics now tied to hospital reimbursement

COMPETITIVE LANDSCAPE

We thread the needle between every incumbent.

COMPETITOR	APPROACH	FATAL WEAKNESS	OUR WEDGE
Epic / FDB Alerts Native EHR	Boolean pop-ups on every order	70–90% dismiss rate (JAMIA). Alert fatigue is a clinical crisis.	Multi-factor engine. Specific. Override-documented.
MDCalc / UpToDate SMART calculators	Reactive reference the doctor must launch	5% usage rate. Used in the cafeteria, not the CPOE.	Proactive. Monitors CPOE silently. Fires before the order is signed.
Bamboo / NarxCare PDMP database	Narx Score from retail pharmacy fills	Outpatient only. Useless for ICU. Black-box backlash.	Owns inpatient. Transparent math. Works where NarxCare doesn't.
AI/ML CDS Startups Predictive AI	ML overdose risk models, hundreds of EHR variables	FDA 2026 requires 510(k). $2M+ / 2 years. CISOs refuse.	Deterministic. Non-SaMD. CISO-safe. Pre-cleared.
Precision Analgesia ✓ SMART on FHIR CDS	Proactive CDS Hook engine, FHIR auto-population, deterministic transparent math	—	Inpatient. Proactive. Non-Device CDS. CISO-safe. Settlement-funded.

REVENUE

From an iOS beta to a $250K/year hospital contract.

PRIMARY REVENUE

Enterprise SaaS — Health System Licensing

$150K–$350K

Annual contract per hospital system — priced as a fraction of one prevented malpractice verdict.

Implementation & onboarding	$15–30K one-time
Base SaaS license	$120–250K/yr
Pharmacogenomics tier	+$50K/yr
Settlement documentation	+$25K/yr

SECONDARY REVENUE

iOS App — Individual Clinicians

Currently free (TestFlight beta). Serves as top-of-funnel — a hospital's CMO downloads the app, uses it at home, champions the enterprise integration. Freemium → institutional subscription path.

Unit Economics (Per Hospital System)

Avg. single preventable opioid verdict	$8–15M
Annual cost of our integration	$150–350K
Hospital ROI (1 prevented event / 10 yrs)	~30x
Settlement abatement eligibility	Exhibit E

Go-To-Market Motion

1. **Epic App Orchard** → inbound discovery from 2,800 hospital network
2. **CMIO champion** path — iOS app creates awareness, CMIO requests enterprise eval
3. **Settlement framing** — hospital legal identifies abatement funding, kills budget objection
4. **Shadow Mode** — 90-day silent run proves error detection rate before go-live

WHERE WE ARE TODAY

Engine built. Ready for the track.

21,000+
Lines of production code (frontend + backend)

25
Clinical React components (6 major workflow modules)

18/18
Backend clinical logic tests passing (pytest)

15
Clinical API endpoints (rate limited + JWT auth)

✅ Built & Verified

- ✓ Full SMART on FHIR R4 patient context ingestion
- ✓ 10-rule Safety Engine + OIRD scoring, OME/MME, renal/hepatic, pharmacogenomics
- ✓ WCAG 2.1 A accessibility (screen readers, keyboard nav, VDI-compliant)
- ✓ Rate limiting + JWT token validation on every clinical route
- ✓ FHIR Write-Back scaffolding (MedicationRequest + DocumentReference)
- ✓ iOS app in TestFlight beta with real clinical users

🚀 Next 30 Days (Post-Seed)

- ○ Generate JWKS keys → register at **fhir.epic.com**
- ○ Prove FHIR R4 on Epic Sandbox synthetic patients
- ○ Wire FHIR Write-Back → live 1-click Naloxone co-prescribing
- ○ AKI trending — last 3 creatinine values, not just today's
- ○ Submit to Epic App Orchard — activate inbound discovery
- ○ Sign first pilot hospital for Shadow Mode deployment

FUNDRAISE

Seed Round — putting tires on the Ferrari.

RAISING

$2.5M

Seed Round — 18-month runway to first signed hospital contracts

Use of Funds

Epic Sandbox → Production Integration	$600K (24%)
Clinical Validation & Pilot Hospital	$700K (28%)
Engineering (AKI, CDS Hooks, Write-Back)	$750K (30%)
Enterprise Sales & CMIO Outreach	$450K (18%)

18-Month Milestones

MONTH 3
Epic Sandbox registration, JWKS keys, FHIR R4 synthetic test passing

MONTH 6
First pilot hospital signed. Shadow Mode live. CDS Hooks on `medication-prescribe`.

MONTH 9
Shadow Mode data proves error detection rate. First $250K contract signed. App Orchard listed.

MONTH 18
5+ hospital contracts. Series A raise. SOC 2 Type II audit.

💡 The Settlement-Funded Sales Insight

Where settlement abatement funding applies, hospitals pay for our integration **without a capital budget approval**. This compresses an 18-month enterprise sales cycle to 4–6 months. Our seed capital funds us to the first 5 settlement-funded contracts.

THE VERDICT

You are not buying a calculator. You are buying a hospital safety mandate.

Every hospital without this tool is writing opioid orders without a safety net. One prevented verdict pays for 50 years of our contract. The clinical engine is built. The regulatory path is clear. The settlement funds are ready.

WEBSITE
precision.lifelinemedtech.org

IOS BETA
TestFlight

COMPANY
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