

WHY ONLY AN INTEGRATED, LINE-AWARE RECORD CAN RUN A MULTI-LINE PRACTICE WITHIN ITS RULES

Five Lines, Five Rulebooks

Each line of care is regulated at a different object, by different law, on a different clock. Software built for one line encodes that line's answers as constants, and those constants are violations in the next line.

Behavioral health

PT, OT and speech

Medical aesthetics

Functional medicine

Primary care and DPC

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Federal regulation text read from eCFR (current to October 2026), CMS manuals, the Federal Register, IRS, FDA, DEA and state statutes. Not legal advice.

THE FINDING

A line of care is not a template. It is a rulebook, and the rulebooks conflict.

65+

federal and state rules mapped across the five lines and the shared rules

5

different regulated objects: the note, the minute, the vial, the lab order, the contract

1 of 4

software set-ups that can enforce every rule for a multi-line practice: the integrated, line-aware record

\$2.19M

yearly HIPAA penalty cap per violation type; False Claims Act adds treble damages per claim

Behavioral health is regulated at the note and every disclosure of it. Therapy is regulated at the minute, the assistant and the calendar. Aesthetics is regulated at the vial, the supervisor and the photo. Functional medicine is regulated at the lab order, the health claim and the supplement. Direct primary care is regulated at the membership contract itself. A platform designed for one of these builds its data model around that object and hard-codes the answers to the others: “one consent”, “units are minutes over 15”, “always file a claim”, “telehealth allowed”. Each of those constants is correct in one line and a violation in another.

That is why a single-line platform cannot run a second line within its rules. It can store the second line’s notes, but it cannot enforce the second line’s rules, and in six places the rules directly contradict each other, so no single setting can satisfy both. The only design that enforces every rule for a multi-line practice is one where the **line of care is a first-class property of every visit and note**, and the rules are applied by line, state, payer, practitioner and date. The test below shows that none of the alternatives does.

Seven gates, five rulebooks

Citations are to the controlling authority; details and verification status in the line sections and sources. “—” means the gate does not arise in that line in the ordinary course.

Gate	Behavioral health	PT, OT and speech	Medical aesthetics	Functional medicine	Primary care and DPC
What the regulator watches	The note and every disclosure of it	The minute, the assistant and the calendar	The vial, the supervisor and the photo	The lab order, the claim and the supplement	The membership contract and the vaccine
Who may act	Psychiatric consultant reviews the Collaborative Care caseload weekly (CMS MLN909432)	PTA/OTA minutes flagged CQ/CO and paid at 85% (42 CFR 410.60(a)(4))	Injectables delegated only under a signed protocol, supervisor on site or reachable (22 TAC §169.26); elective IV only by RN/PA/APRN (Tex. Occ. Code ch. 172)	Only a person state law authorises may order a lab test (42 CFR 493.2, 493.1241; 10 NYCRR 58-1.7)	HSA-eligible DPC fee covers primary-care practitioners only (Pub. L. 119-21; IRS Notice 2026-5)
Before care starts	Part 2 consent with all required elements, never bundled with counseling-note consent (42 CFR 2.31)	Written plan of care before treatment; certification within 30 days (42 CFR 410.61, 424.24(c))	Prior exam by a prescriber before any injectable (Cal. B&P §2242; R.I. Gen. Laws §23-105-2)	Good Faith Estimate to self-pay patients (45 CFR 149.610)	Signed DPC agreement with the statutory “not insurance” statement (Fla. Stat. §624.27); Medicare private contract signed before care (42 CFR 405.415)
Privacy and consent	Psychotherapy notes separated, separate authorisation (45 CFR 164.501, 164.508(a)(2)); notice on every Part 2 disclosure (42 CFR 2.32)	Standard HIPAA treatment, payment and operations	Marketing authorisation per photo (45 CFR 164.508(a)(3)); before/after disclosures (16 CFR 255.2(b))	Health claims need RCT-grade evidence (FTC Health Products Guidance, 2022)	Minors, VFC eligibility and registry reporting rules by state
The clock	Psychotherapy billed by session minutes; Collaborative Care by monthly minutes (70/60/30)	8-minute unit bands (Pub. 100-04 Ch. 5 §20.2); progress report every 10 treatment days; recertify every 90 days	Adverse events reported before the patient leaves (R.I.) or within 15 days (Indiana, 2027)	Schedule III testosterone: 5 refills within 6 months (21 CFR 1306.22)	Opt-out affidavit within 10 days; 2-year renewal (42 CFR 405.410); registry reporting within 14 days (N.Y. PHL §2168)
How money may flow	Time-based codes; CoCM requires registry, consent and consultant to bill	\$2,480 KX threshold, \$3,000 review threshold per beneficiary (SSA §1833(g)); 50% practice-expense reduction for extra units	Cash and retail; cosmetic is not §213(d) medical care; retail cosmetics taxable	Cash, superbills; supplements HSA-eligible only with a letter of medical necessity (IRS Pub. 502)	No insurance claim for covered services (Fla. §624.27; Notice 2026-5); fee ≤ \$150/\$300 a month for HSA

Gate	Behavioral health	PT, OT and speech	Medical aesthetics	Functional medicine	Primary care and DPC
Product, drug and lab	EPCS for controlled substances (21 CFR 1311); PDMP checks in 48 states	—	Botox lot and expiry; purchases reconcile with units given (DSCSA §582(d); FDA warning letter, Apr 2026)	CLIA ordering vs performing; compounded hormones and peptides limited (FD&C §503A)	Vaccine manufacturer and lot, VIS before each dose (42 U.S.C. §§300aa-25, -26)

Six collisions: one line's required action is another line's violation

If the lines only had different rules, a single-line platform could in principle add settings. They have contradictory rules. One setting cannot satisfy both sides of these pairs, so the rule has to be chosen per visit, by line.

File the claim, or never file it

Primary care and DPC

A DPC agreement is “not insurance” only if the provider will not file claims for covered services (Fla. Stat. §624.27); billing members through insurance can cost the HSA status (IRS Notice 2026-5).

VS

PT, OT and speech

Therapy revenue exists only as Medicare and payer claims built from 8-minute units, KX accumulators and CQ/CO modifiers (Pub. 100-04 Ch. 5).

Result: An insurance EHR's default action voids the DPC safe harbour. A DPC platform's default leaves therapy unbilled.

Release the record, or withhold it

Behavioral health

Psychotherapy notes need a separate authorisation; Part 2 records travel only with consent and a notice (45 CFR 164.508(a)(2); 42 CFR 2.31–2.32).

VS

Primary care and DPC

Providers are information-blocking “actors” who must not impede access to the rest of the record (45 CFR 171.103).

Result: The same export button must release one data class and refuse another, by line and by note type.

Telehealth after 2027

Behavioral health

Home tele-mental-health continues after 31 Dec 2027, with an in-person visit clock per patient (SSA §1834(m)).

VS

PT, OT and speech

From 1 Jan 2028, PTs, OTs and SLPs can no longer furnish Medicare telehealth (CMS FAQ, 8 Oct 2026).

Result: A single telehealth policy is wrong for one of the two lines on the same day.

One membership, two tax answers

Medical aesthetics

Cosmetic procedures are not §213(d) medical care, and retail cosmetics are taxable (26 U.S.C. §213(d)(9); IRS Pub. 502).

VS

Primary care and DPC

A DPC fee is HSA-compatible only if it buys solely primary care, at ≤ \$150 a month per person (Pub. L. 119-21; Notice 2026-5).

Result: Bundle a med spa credit into the DPC fee and every member loses HSA eligibility.

Three ways to count time

Behavioral health

Psychotherapy: session minutes pick the code; Collaborative Care: care-manager minutes summed per calendar month.

vs

PT, OT and speech

Therapy: all timed minutes for the day convert to units by the 8-minute band, split by who delivered them (PT vs PTA).

Result: The same 40 minutes is one code in one line and three units, possibly at 85%, in the other.

Three drug ledgers

Medical aesthetics

Neurotoxins: lot, expiry and purchase-to-administration reconciliation under the drug supply-chain law (DSCSA).

vs

Functional medicine

Testosterone: a Schedule III record of administration, refill limits and a biennial inventory (21 CFR 1304, 1306).

Result: Primary care adds a third: vaccine lot, VIS and registry feed. One inventory model cannot satisfy all three.

Every way to run two lines, tested against the rules

A practice that runs more than one line has four ways to set up its software. Only one of them can enforce every rule below in software. The other three either break a rule outright, or leave the rules that span lines to manual checks that no system can verify.

WHAT A MULTI-LINE PRACTICE MUST DO	ONE SINGLE-LINE PLATFORM	TWO SINGLE-LINE PLATFORMS	A GENERAL MULTISPECIALTY EHR	ONE INTEGRATED, LINE-AWARE RECORD (MEDOP)
Apply each line's own time, unit and code rules to its own visits	✗ Only its own line's rules exist	✓	🕒 Generic rules; staff apply the line rules by hand	✓ Rules chosen by the visit's line
File claims for therapy and behavioral health, but never for a service a DPC membership covers	✗ Hard-coded: always claim, or never claim	🕒 Holds only while every patient and service is in the right system	✗ Claims are the default action	✓ Claim refused for a covered service
Keep a member's DPC fee HSA-compatible when the same member also buys aesthetics or supplements	✗ No membership rules for the other line	✗ Neither system can see the other's charges	✗ No membership or HSA rules	✓ Plan checked against HSA rules before publishing; other lines sold separately
Share allergies and medications across lines while withholding psychotherapy notes and Part 2 records	✗ No second line to share with	✗ Share everything or nothing	🕒 Role-based access, not line-based	✓ Shared core; notes walled by line; AI scoped by line
Run three drug ledgers: neurotoxin lot reconciliation, Schedule III records, vaccine lots	✗ One product model	🕒 Each system runs only its own ledger	🕒 Generic inventory	✓ Lot, expiry, vaccine and controlled-substance registers on one record
Give the patient one record, one portal and one bill	✗ Second line cannot be represented	✗ Two of each	✓ Yes, without line rules	✓ Yes, with line rules
Requirements met in software	0 of 6	1 of 6	1 of 6	6 of 6

1 of 4

For any practice running two or more lines of care, only an integrated record that knows each visit's line can enforce that practice's regulatory gates in software. A single-line platform cannot represent the second line's rules; two platforms cannot see across each other; a general EHR has no line-specific gates. Each of those practices is left relying on staff to catch, by hand, the rules that carry HIPAA, False Claims Act, DEA, FTC, state-board and tax consequences.

REGULATED OBJECT

Behavioral health

The note and every disclosure of it

RULE	AUTHORITY	THE GATE SOFTWARE MUST ENFORCE	IF IT IS NOT ENFORCED
Psychotherapy notes are a separate record class, released only with a separate authorisation	45 CFR 164.501; 164.508(a)(2)	Separate note type kept out of the chart view, exports, portal and AI context	Each impermissible disclosure: \$145–\$2,190,294 per violation, \$2.19M yearly cap (45 CFR 102.3, 2025 amounts)
Part 2 consent with required elements; SUD counseling notes need their own consent; notice on every disclosure; 3-year accounting	42 CFR 2.31, 2.32, 2.25 (compliance 16 Feb 2026)	Structured consent object; sensitivity tag on each data element; disclosure ledger	Enforced through HIPAA penalties since 16 Feb 2026
Minors who consent to SUD treatment alone control disclosure, including to a parent for payment	42 CFR 2.14(a)	Billing must not send a statement or claim that reaches a parent without consent	The statement itself becomes an unauthorised disclosure
Psychotherapy codes are time-based	NCCI Policy Manual Ch. XI; LCD L35101	Code derived from documented minutes, not chosen freely	Upcoding exposure: False Claims Act \$14,308–\$28,619 per claim plus treble damages
Collaborative Care: registry, consent, psychiatric consultant, 70/60/30 minutes a month	CMS MLN909432 (Jan 2026)	Registry with minute accrual per calendar month	Denial or recoupment
Measurement-based care with a standardised tool	Joint Commission CTS.03.01.09	Instrument schedule and trend in the treatment plan	Accreditation finding

WHY A SINGLE-LINE PLATFORM FAILS

A general or single-line EHR assumes one consent, one note type and one chart every treating user can see. Behavioral health breaks all three. Retrofitting segmentation is a data-model change, because every historical record must be re-tagged.

HOW MEDOP ENFORCES IT

Psychotherapy CPT minute bands checked against session time; Collaborative Care registry, time ledger and month close; Part 2 marked per record with consent and disclosure accounting; PHQ-9, GAD-7 and PCL-5 on a schedule; psychotherapy notes and Part 2 records withheld from other lines and from every AI agent.

REGULATED OBJECT

PT, OT and speech

The minute, the assistant and the calendar

RULE	AUTHORITY	THE GATE SOFTWARE MUST ENFORCE	IF IT IS NOT ENFORCED
Timed codes convert to units by the 8-minute rule across the day	Pub. 100-04 Ch. 5 §20.2	Minutes captured per code; units computed, never typed	Overpayment; a systematic pattern is a False Claims Act exposure
KX threshold \$2,480 (PT/SLP and OT separately, 2026); targeted review at \$3,000	SSA §1833(g); CMS CR 14252	Running accumulators per beneficiary per year	Denial without KX; routine KX use called abusive
Plan of care before treatment; certification within 30 days; recertify every 90	42 CFR 410.61; 424.24(c)	Plan object that blocks notes without an active, certified plan	Every visit under a missing plan is non-covered
Progress report every 10 treatment days	Pub. 100-02 Ch. 15 §220.3	Treatment-day counter that flags the 11th visit	Visits lack medical-necessity support
Assistant minutes carry CQ/CO and are paid at 85%, with a 10% de minimis test	42 CFR 410.59(a)(4), 410.60(a)(4)	Per-unit, per-clinician minute capture	About 15% overpayment per affected unit
Direct access limits: 21 states unrestricted, 29 + DC provisional	State practice acts (APTA, Jul 2025)	Visit or day counter without a referral, by state	Practice-act violation

WHY A SINGLE-LINE PLATFORM FAILS

Therapy revenue integrity is arithmetic on minutes, people and calendars that no other line uses. A behavioral-health or primary-care EHR bills a 60-minute visit as one code, has no assistant modifier and certifies nothing; its failure is silent until a medical review recoups claims in bulk.

HOW MEDOP ENFORCES IT

The Medicare 8-minute units computed from treatment minutes; a KX threshold ledger per discipline; CQ and CO modifiers from who performed the minutes; plan-of-care certification windows and progress-note reminders; 59 and X modifiers proposed with a recorded reason; MIPS measures.

REGULATED OBJECT

Medical aesthetics

The vial, the supervisor and the photo

RULE	AUTHORITY	THE GATE SOFTWARE MUST ENFORCE	IF IT IS NOT ENFORCED
A prescriber's prior exam before any injectable	Cal. B&P §2242(a); R.I. Gen. Laws §23-105-2	No injectable order or delegated administration without a current exam on the chart	Unprofessional conduct; board discipline
Delegation only under a signed protocol, with the supervisor on site or reachable; elective IV only by RN/PA/APRN	22 TAC §§169.25–.28; Tex. Occ. Code ch. 172 (2025)	Role- and protocol-based block on who may chart what	Unlicensed practice of medicine
Med spa registration, responsible practitioner and 15-day adverse-event reporting	Indiana SEA 282 (from 2027); R.I. Medical Spas Safety Act	Adverse-event log with reporting clock; location registration	Fines up to \$5,000; operating unregistered
Neurotoxins bought only from authorised partners; purchases must reconcile with units given	DSCSA, FD&C §582(d); FDA warning letter, 1 Apr 2026	Lot and expiry per administration; purchase-to-use reconciliation	Seizure and injunction warning
Before/after photos need typical-results disclosure and a marketing authorisation	16 CFR 255.2(b); 16 CFR 465; 45 CFR 164.508(a) (3)	Per-photo consent, expiry and takedown	\$53,088 per violation (FTC Consumer Reviews Rule)
Cosmetic is not medical care; retail cosmetics taxable	26 U.S.C. §213(d)(9); N.Y. Tax Law §1115	Line-item classification of every charge	Wrong HSA receipts; sales-tax liability

WHY A SINGLE-LINE PLATFORM FAILS

An aesthetics practice is regulated through the drug supply chain, the supervision graph and its marketing, not through payer claims. A therapy or behavioral-health EHR has no exam gate, no supervisor-to-location rule, no lot reconciliation and no photo consent; a commerce-first med spa platform sells the treatment without the medical gates.

HOW MEDOP ENFORCES IT

No injectable signed without a current Good Faith Exam; injectables tracked by lot and expiry, and an expired lot cannot be charted; supervision attestation and an adverse-event log; face maps with units per site; photos under patient-managed consent; packages, memberships, retail and manufacturer rewards on the same chart.

REGULATED OBJECT

Functional medicine

The lab order, the claim and the supplement

RULE	AUTHORITY	THE GATE SOFTWARE MUST ENFORCE	IF IT IS NOT ENFORCED
Only state-authorized persons may order tests; ordering and performing are separate	42 CFR 493.2, 493.1241; 10 NYCRR 58-1.7; Md. Health-Gen. §17-215	State matrix of who may order; lab CLIA ID stored	Unauthorized ordering; lab-law violations
AI protocol drafting must stay clinician-facing, non-directive and reviewable	FD&C §520(o)(1)(E); FDA CDS guidance (Jan 2026)	Drafts go only to clinicians, with the basis shown; a clinician decides	Device regulation of the software
Health claims need competent and reliable evidence	FTC Act §§5, 12; Health Products Compliance Guidance	Claims register tied to evidence	FTC enforcement
Testosterone is Schedule III: refill limits, records, inventory	21 CFR 1306.22, 1304.03, 1304.11	Controlled-substance ledger; telemedicine flag to 31 Dec 2026	DEA recordkeeping penalty \$19,246 per violation
Compounded hormones and peptides only within §503A lists	FD&C §503A; FDA bulks lists	Formulary block on non-listed bulk substances	Adulterated or misbranded drug
Supplements HSA-eligible only with a letter of medical necessity; Good Faith Estimate for self-pay	IRS Pub. 502; 45 CFR 149.610	LMN tied to diagnosis and product; superbill	Ineligible reimbursements; estimate disputes

WHY A SINGLE-LINE PLATFORM FAILS

Functional medicine's defining activity is broad specialty lab ordering and protocol recommendations, usually for cash. That creates gates an insured primary-care or aesthetics system lacks: a state ordering matrix over CLIA, a claims register, a controlled-substance ledger, a compounding formulary and HSA paperwork instead of payer claims.

HOW MEDOP ENFORCES IT

Protocols never edited in place, only versioned; a 122-marker lab catalog with cross-lab trends; lab PDFs imported row by row and verified by a clinician before anyone sees them; drafting agents that address clinicians only, cleared after counsel's clinical-decision-support review; superbills and HSA/FSA receipts.

REGULATED OBJECT

Primary care and DPC

The membership contract and the vaccine

RULE	AUTHORITY	THE GATE SOFTWARE MUST ENFORCE	IF IT IS NOT ENFORCED
DPC agreement is “not insurance” only with statutory terms and a “will not file claims” statement	Fla. Stat. §624.27 (34 states have DPC laws)	Agreement template validated before publishing; kept as signed	Regulated as unlicensed insurance
HSA-compatible DPC: primary care only, ≤ \$150/\$300 a month, no drugs except vaccines	Pub. L. 119-21 §71308; IRS Notice 2026-5	Plan validator for fee cap, practitioners and excluded services	Every member loses HSA eligibility
Medicare opt-out: private contract signed before care; affidavit within 10 days	42 CFR 405.410–405.415	Contract engine per Medicare-age member; affidavit clock	Opt-out void; all claims must be filed
Vaccine lot, manufacturer and VIS before each dose; VFC eligibility	42 U.S.C. §§300aa-25, -26, 1396s	Lot capture, VIS record, eligibility screen	VFC program breach; record deficiencies
Immunization registry reporting (e.g. within 14 days in New York)	N.Y. PHL §2168; 70% of jurisdictions (AIRA)	Per-state registry connector	Public-health reporting violation
Hybrid practices billing Medicare need certified EHR use for MIPS	42 CFR 414.1375, 414.1405	Certified modules and measure reporting	Up to –9% on Part B

WHY A SINGLE-LINE PLATFORM FAILS

In DPC the membership itself is the regulated object, checked at once against state insurance law, federal tax law and Medicare. An insurance-billing EHR assumes a claim is always allowed: the exact act that breaks the DPC safe harbour and the Medicare opt-out. An aesthetics or functional-medicine platform has no fee-cap validator, no opt-out contract engine and no registry connector.

HOW MEDOP ENFORCES IT

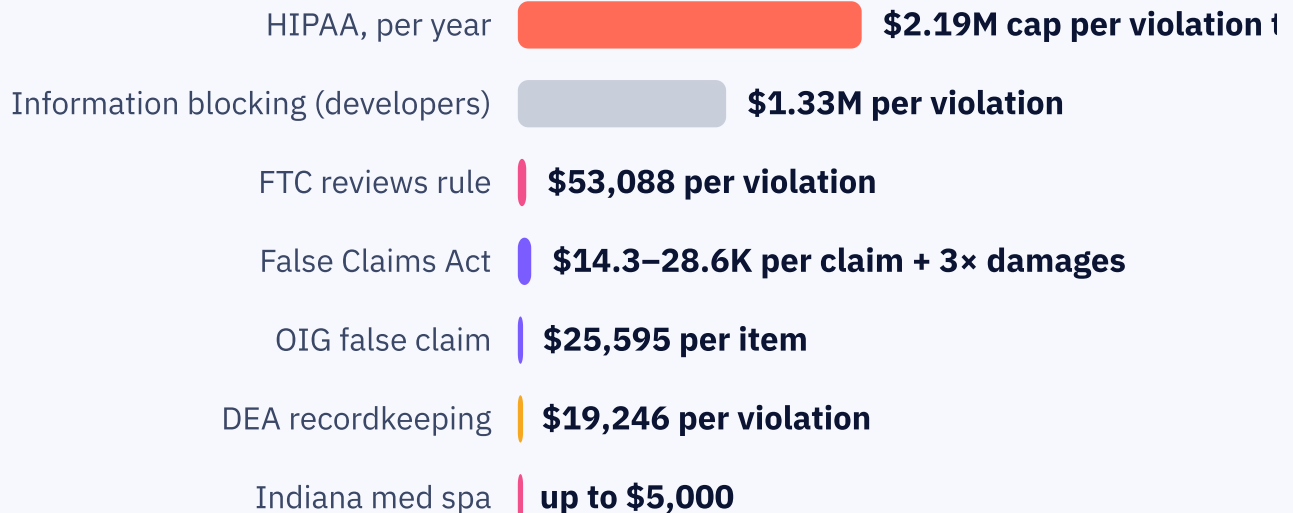
One membership engine with plans checked against Florida’s DPC statute, a model-act baseline, HSA and Medicare rules before publishing; plan versions frozen once members join; agreements signed in the portal and kept as signed; no insurance claim for a covered service; immunizations and growth charts, with registry submission built per state.

THE SHARED RULES

Even the shared rules apply differently by line

- **Controlled substances:** e-prescribing of controlled substances requires two-factor signing, identity proofing, two-person access control, daily audit review and a two-yearly third-party audit (21 CFR 1311). It is central to psychiatry and testosterone therapy, and rare in therapy. 48 states plus DC mandate prescription-monitoring checks with different triggers; DEA telemedicine flexibilities run only to 31 December 2026 (90 FR 61301).

- **Information blocking** requires a provider to release data, while psychotherapy-note and Part 2 rules require withholding it. The exception logic is line-specific (45 CFR 171).
- **Billing integrity:** every time band, unit, modifier and threshold above exists to prevent claims that are false by construction. The False Claims Act penalty is \$14,308–\$28,619 per claim plus treble damages (28 CFR 85.5).



Maximum penalties behind the gates (2025–26 amounts). HIPAA 45 CFR 102.3 (91 FR 3665); FCA 28 CFR 85.5; OIG 45 CFR 102.3; DEA 21 U.S.C. §842; FTC 16 CFR 465. Bars on a log-like scale are not used; the HIPAA bar is capped for readability.

THE WORKAROUND

Why “two systems” does not solve it

Practices that run two lines today usually run two platforms. That keeps each rulebook in its own system, but the rules that matter most span the lines and cannot be checked by either system alone:

- **HSA status depends on the whole membership.** Whether a DPC fee stays HSA-compatible depends on what else the member is billed and bundled (Notice 2026-5). A DPC system cannot see the med spa system’s charges.
- **Part 2 and minors control billing.** Whether a statement may go to a parent depends on the SUD consent held in the behavioral-health system (42 CFR 2.14(a)); the other system sends it anyway.
- **Safety needs the whole patient.** The injector needs allergies and medications, but must never see psychotherapy notes. The clinician needs to know a body-dysmorphia screen exists. Two systems either share everything or nothing.
- **Two records drift.** Medications, allergies, consents and contact preferences diverge, and the patient gets two portals and two bills.

One record, with the line of care as a first-class property

WHAT MEDOP DOES

Every visit and note carries its line. The line decides which codes, templates, time rules, consent gates and billing rules apply at the moment of signing. Demographics, insurance, allergies, medications, problems, consents, the portal and the statement are shared. Notes, templates, codes and rules stay in their line. Psychotherapy notes and Part 2 records never cross without consent, and every AI agent sees only the line of the visit it is serving. Staff in another line see that a record exists, and opening it is a deliberate, audited act.

STATED PLAINLY

Some rule packs and templates are drafts awaiting clinical, billing or counsel review; DPC rule packs cover Florida, with other states drafted. Controlled-substance e-prescribing is built and switched off until production verification. Prescription-monitoring checks and state minor-consent rules are not yet built. A practice's own counsel remains responsible for its compliance.

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Aesthetics, functional medicine and primary care

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Some items could be confirmed only through secondary sources: the numeric psychotherapy minute bands; California's minor-consent statute; Indiana SEA 282; New York's patient-specific order rule for RN injectables; the DPC state count (DPC Coalition); immunization-registry percentages (AIRA, 2021). This paper is analysis, not legal advice.