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The 60-Day Federal Pathway

What every state-medical cannabis cultivator must do before the window closes.

A step-by-step transition roadmap for state-licensed cannabis cultivators applying for DEA registration under 21 CFR § 1301.13(k). Covers eligibility, document assembly, application mechanics, public-interest defense, post-registration operational obligations, and the buy/sell-back nominal-price mechanism. Includes a complete pre-submission checklist.

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A Transition Primer

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Authorities cited: AG Order No. 6754-2026 (final rule, FR Doc. 2026-08176); 91 Fed. Reg. 22,714 (Apr. 28, 2026); AG Order No. 6753-2026 (Notice of Hearing on Proposed Rulemaking); AG Order No. 6752-2026 (Withdrawal of 2024 NPRM); 21 U.S.C. §§ 811(d)(1), 822, 823, 825, 827; 21 CFR Parts 1300, 1301, 1308, 1312, 1318.

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0. Read-Me-First Summary

On **April 28, 2026**, the U.S. Department of Justice published a final rule (AG Order No. 6754-2026) placing two narrowly defined categories of marijuana into **Schedule III** of the Controlled Substances Act:

1. FDA-approved drug products containing marijuana, and
2. **Marijuana, marijuana extracts, and naturally-derived Δ9-THC subject to a state-issued license to manufacture, distribute, or dispense marijuana for medical purposes.**

For a **state-licensed cannabis cultivator**, three things changed on that date:

- A federal license — **DEA registration** — is now both *available* and *required* to keep operating lawfully under federal law for the medical scope of your state license.
- A **60-day expedited window** (closing in late June 2026 — see § 8) lets cultivators with a qualifying state medical license file under the new pathway and **continue operating under the state license while DEA reviews** the application.
- For the first time, a U.S. cultivator can lawfully **import and export** state-licensed medical cannabis under DEA permit, supply DEA-registered researchers, and exit IRC § 280E for the medical line of business.

This primer is a step-by-step transition roadmap. It is **not** a GMP overlay — that is a separate workstream. It is the federal-licensing baseline that every state medical cultivator must clear before any other federal-track work (cGMP, EU-GMP, IND/NDA, export) can begin.

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1. Eligibility Gate — Do You Qualify?

Before you spend a dollar on a federal application, confirm five eligibility facts. If any one is "no," fix it first.

#	Question	Required Answer
1	Do you hold a current, valid **state-issued license** authorizing you to **manufacture / cultivate** marijuana?	Yes
2	Does that license authorize the activity for **medical purposes** (as defined by your state's regulator)?	Yes
3	Is your activity inside the federal definition of **marijuana** (21 U.S.C. § 802(16))?	Yes (most cultivators are)
4	Is your activity **not** limited to: synthetically derived THC (Δ-8, Δ-10, synthetic Δ-9), hemp under 7 U.S.C. § 1639*o*, or adult-use only?	Yes — those remain Schedule I or are otherwise out of scope
5	Is your state license **clean** — no active suspensions, revocations, or pending disciplinary action?	Yes (a state suspension auto-suspends your future DEA registration — § 1301.13(k)(3))

Adult-use only operators are not eligible. The final rule rescheduled marijuana subject to a state *medical* license. Adult-use marijuana — even if state-licensed — remains Schedule I. Operators with combined medical + adult-use licenses can register under § 1301.13(k) **only for the medical scope**, and must operationally segregate the two streams (see § 9).

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2. The Two-Pathway Architecture

DEA created **one new regulatory subsection** — 21 CFR § 1301.13(k) — and one new set of Schedule III drug-code entries — 21 CFR § 1308.13(g)(2)–(4) — to cover state-medical operators. Within § 1301.13(k) there are three registration types (§ 1301.13(k)(1)):

Type	Scope	DEA Form	Fee	Period
Manufacturer (cultivator/ processor)	Cultivate, produce, process, package, label, and transfer marijuana to registered distributors or manufacturers, **subject to the limitations of state license**	**Form 225**	$3,699 / yr	1 yr
Distributor	Receive from registered manufacturers; transfer to registered dispensers or distributors	Form 225	$1,850 / yr	1 yr
Dispenser (retail/ dispensary)	Dispense to state-authorized patients/ caregivers	**Form 224**	$888 / 3 yr (+ $794 medical-marijuana dispensary application fee per DEA portal)	3 yr

> **Cultivators apply as MANUFACTURERS.** Per § 1301.13(k)(1)(A), a "registered marijuana manufacturer may cultivate, produce, process, package, label, and transfer." Cultivation is explicitly within the manufacturer category.

A single legal entity may stack multiple registration types under § 1301.13(k)(1)(E) — a vertically integrated cultivator/processor/distributor pays multiple fees and files separately for each business activity, but federal scope **cannot exceed state scope**.

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3. The Three New Drug Codes

Every § 1301.13(k) application must identify the drug codes the registrant intends to handle. The DEA online portal currently lists these as:

Drug Code	Substance	Source
7362	Marijuana (21 U.S.C. § 802(16)) in an FDA-approved product or subject to a state medical marijuana license	21 CFR § 1308.13(g)(2)
7353	Marijuana extract (21 CFR § 1308.11(d)(58)) in an FDA-approved product or subject to a state medical marijuana license	21 CFR § 1308.13(g)(3)
7386	Naturally derived Δ9-THC in an FDA-approved product or in marijuana subject to a state medical marijuana license	21 CFR § 1308.13(g)(4)

A cultivator who sells flower and trim only typically requests **7362**. A cultivator who also operates an extraction line adds **7353**, and an isolate/distillate operator who isolates Δ9-THC from extract adds **7386**. Identify the *narrowest* set that matches your state license — you can amend the registration later.

> **Watch for code confusion.** The older Schedule I codes 7350 (Marijuana) and 7360 (Extract) **still exist** and still cover unlicensed bulk material. They are NOT the new codes. Some early industry briefings have published the wrong code triple. The correct new Schedule III codes for state-medical registrants are 7362 / 7353 / 7386 as listed above.

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4. Pre-Application Document & Data Pack

Begin assembling these before you log into the DEA portal. Most denials and delays come from missing or inconsistent documentation, not from substantive ineligibility.

4.1 Business identity

- Legal entity name + DBA(s)
- Business address + mailing address
- Phone, business email, contact person, contact cell + email
- Federal EIN (or SSN if sole proprietorship)
- Organization type: C-corp / S-corp / LLC / partnership / LLP / sole prop / other
- Past-12-month ownership change disclosure (Y/N + detail)
- Existing DEA registrations held by the firm (Y/N + numbers)
- Past controlled-substance handling experience (Y/N + detail)

4.2 State authorization (§ 1301.13(k)(2))

- State license number, issuing state, expiration date — for **every** state license under which the federal scope will operate
- A clean copy of each license (a state license is **conclusive evidence** of state authorization for purposes of 21 U.S.C. § 823(e)-(g))

4.3 Liability disclosures (§ 1301.13(k) registration cannot exceed scope of a clean state license)

- Any controlled-substance criminal conviction (state or federal) — applicant or any officer/partner/stockholder/proprietor (non-public companies)
- Any prior **federal** controlled-substance registration surrender (for cause), revocation, suspension, restriction, denial — applicant or any officer/partner/stockholder/proprietor — including pending actions
- Any prior **state** professional license or controlled-substance registration surrender (for cause), revocation, suspension, restriction, denial, or probation — applicant or any officer/partner/stockholder/proprietor — including pending actions
- Any Medicare/state-health-program exclusion or pending exclusion
- Any unregistered controlled-substance manufacture, distribution, or dispensing by anyone in ownership/operation

> **Public-Interest Factor caveat.** Even with truthful "yes" answers, registration is not automatically denied. But every yes triggers DEA's discretionary public-interest review under 21 U.S.C. § 823(e)-(g). Prepare written context for each.

4.4 Activity scope (§ 1301.13(k)(1))

- Are you handling/dispensing **medical** marijuana? (Y)
- Are you handling/dispensing **recreational** marijuana? (If Y, that scope is **not** covered by this registration and must be operationally segregated from the federal scope.)

- National Provider ID (if applicable — typically only for prescriber-adjacent activity)

4.5 Cultivation-specific data — the most-overlooked piece

The final rule requires that a **manufacturer registration "shall specify the areas in which marijuana cultivation is permitted"** (§ 1301.13(k)(6)(C)). For a cultivator, this means:

- **Legal descriptions or parcel/APN numbers** for every grow location: indoor cultivation rooms, greenhouses, outdoor parcels, tissue-culture labs, mother/clone rooms, drying/curing rooms.
- **Floor plans** showing each cultivation area, with adjacencies to processing, storage, and any non-cultivation activities.
- A clear delineation between cultivation areas under federal scope (medical) and any cultivation areas dedicated to non-federal activity (adult-use, hemp, R&D under separate licenses).
- Any **off-site** locations (e.g., separate drying barns, off-site nurseries) used for cultivation activities.

Federal scope cannot be broader than what your state license permits, so each cultivation location listed must be on or supported by your state license.

4.6 Personnel access list

For every person who will have access to controlled substances at the registered location: - Name, title(s), date of birth, SSN - Existing DEA registration number (if any) - State/territorial authorizations to handle controlled substances - Federal/state/territorial/tribal disciplinary history (Y/N + detail) - Federal/state/territorial/tribal/local controlled-substance offenses (Y/N + detail)

4.7 Security profile (per location)

DEA will accept state-law-compliant physical security under § 1301.13(k)(10), but you must document what you have: - Vault and/or safe specifications - Secure storage room(s) and other secure storage - Premises access controls (key, fob, keycard, PIN, biometric, etc.) - Alarm system specifications (zones, monitoring, response) - On-site security personnel (Y/N, hours, license)

4.8 SOPs (existence audit)

DEA asks whether the firm has SOPs for each of the following. Have a current, dated, signed-off SOP available for **each**: - Ordering - Receiving - Inventories (initial + biennial) - Storage of marijuana - Security - Dispensing (including delivery, if applicable) - Distributing - Destruction / disposal - Theft / loss reporting - Due diligence (supplier/practitioner verification) - Corresponding responsibility - Maintenance of records

If any SOP is missing, build it before you submit. Submitting "no" to an SOP question is not disqualifying, but it is a documented invitation for DEA to scrutinize that activity area.

4.9 Supplier and downstream partners

- For every supplier from whom you will procure marijuana (clones, seeds, extracts, finished product): name + DEA registration number. Suppliers without DEA registration are not lawful federal trading partners for the medical scope.
- For every downstream registered distributor or manufacturer to whom you will transfer: name + DEA registration number.
- Anticipated repackaging or relabeling activities (Y/N).

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5. The Application Mechanics

5.1 Where to file

Cultivators (manufacturers) and distributors file through the **standard DEA Diversion Control online portal**: `https://www.deadiversion.usdoj.gov/`. Only online submissions are accepted.

> **Caution.** A separate portal (`mmapplication.diversion.dea.gov`) opened on April 29, 2026 specifically for **medical marijuana dispensary** applicants. That portal is for **Form 224** (dispensers) only. Cultivators must use the standard Diversion portal and **Form 225**.

5.2 Forms

Activity	New	Renewal
Manufacturer (cultivator)	Form 225	Form 225a
Distributor	Form 225	Form 225a
Dispenser	Form 224	Form 224a

5.3 Fee + payment

- Manufacturer: **$3,699 / year**, paid at submission. Generally non-refundable (limited exceptions at Administrator's discretion under § 1301.13(e): duplicate payment, payment for incorrect business activity, DEA error, registrant death within first year of cycle).
- The dispensary portal currently only accepts **PayPal**; the standard Diversion portal accepts the usual methods.

5.4 Signature

Per § 1301.13(j), the application must be signed by: - The applicant (if individual); - A partner (if partnership); or - An officer (if corporation, division, association, trust, or other entity).

A power of attorney can authorize a non-officer signer if filed with DEA's Registration Unit in advance. The POA is valid until revoked.

5.5 What you submit (the seven sections)

1. **Personal/business information** (§ 4.1)
2. **Activity** — drug codes 7362 / 7353 / 7386 as applicable; medical Y/N; recreational Y/N (§ 4.4)
3. **State license(s)** (§ 4.2)
4. **Liability questions** (§ 4.3)
5. **Compliance information** — suppliers, SOPs, personnel, security (§§ 4.6–4.9)
6. **Payment**
7. **Submission and attestation** — confirmation email returned to the business email; printable confirmation for records.

For a cultivator, expect to attach (or be prepared to attach on follow-up): state license copies, parcel descriptions for each cultivation area, floor plans, security plan, and any ownership-disclosure attachments.

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6. The Public-Interest Defense (21 U.S.C. § 823(e)–(g))

Section 1301.13(k) creates a **presumption** of registration:

> "The Administrator **shall** register an applicant under this subsection unless the Administrator determines that the issuance of such registration is inconsistent with the public interest, taking into account the factors set forth at 21 U.S.C. § 823(e)-(g), as applicable, and the requirements of the Single Convention on Narcotic Drugs."

But the rule's commentary signals DEA will deny where the **underlying state file is dirty**. Build a written "public-interest defense" memo before you file. Address each of the § 823 factors:

- **Maintenance of effective controls against diversion** — METRC reconciliation, transport-manifest integrity, theft/loss history, cycle-count discrepancy log, surveillance coverage, badge/access logs.
- **Compliance with state and local laws** — current state license in good standing, no active enforcement actions, all corrective actions closed.
- **Prior conviction record** — disclose and contextualize any controlled-substance, fraud, or financial-crime history of any officer/owner.
- **Past experience in distributing/dispensing** — operating history, METRC pedigree, third-party audit results (CSQ, ISO, GMP Collective, ASTM, USP-aligned).
- **Public health and safety** — recall history, lab COA retention, adverse-event handling, packaging/labeling compliance.
- **Single Convention requirements** — quota awareness, recordkeeping retention.

Operators with state-level warning letters, METRC discrepancies, lab-shopping histories, or unresolved enforcement actions should remediate **before** submitting. The window is 60 days, but a complete and clean public-interest record is more valuable than a fast filing.

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7. Cultivator-Specific Operational Requirements Once Registered

The final rule grants meaningful relief from federal Part 1300-series requirements **where state law already imposes equivalents**, but several federal minimums apply with no state substitute. As a cultivator, plan for the following operating posture from day one of federal authorization.

7.1 The Single-Convention buy/sell-back (§ 1301.13(k)(6)(A)–(B))

This is the single most operationally novel piece of the new framework, and it applies to **every registered cultivator**.

The two-layer regulatory structure — read this carefully. Article 23 of the Single Convention requires the U.S. government to operate as the exclusive purchaser/wholesaler of cannabis crops. DEA satisfies this through 21 CFR Part 1318, which defines "**medicinal cannabis**" (per § 1318.02(b)) narrowly as "*a drug product made from the cannabis plant, or derivatives thereof, that can be legally marketed under the [FD&C Act]*" — i.e., **only FDA-approved drug products**. Under § 1318.04(b), medicinal cannabis is exempt from the wholesale-trade monopoly.

State-licensed medical marijuana is **not** "medicinal cannabis" under this federal definition (it is not FDA-approved). The final rule therefore handles state-medical operators on a **separate track**:

- § 1301.13(k)(6) opens with: *"Part 1318 shall not apply to entities holding valid licenses under this subsection."* — i.e., the Part 1318 wholesale-trade monopoly mechanism does not directly govern state-medical operators.
- But § 1301.13(k)(6)(A)–(B) **immediately re-imposes** a parallel nominal-price purchase-and-resale obligation directly on state-medical manufacturers, satisfying Article 23 through this dedicated subsection rather than through Part 1318.

Net effect for cultivators: the buy/sell-back applies to every registered state-medical manufacturer, but through § 1301.13(k)(6) — not through Part 1318. Industry alerts that describe state licensees as broadly "exempt from the wholesale-trade monopoly" are imprecise; the exemption is from Part 1318's mechanism, while the substantive obligation persists through the § 1301.13(k)(6) override.

The four-step workflow (per § 1301.13(k)(6)(A)–(B)):

1. The manufacturer **establishes a nominal price** for each crop.
2. The **DEA "purchases"** the crop at that price.
3. **DEA "resells"** the crop back to the same manufacturer (or a related/subsidiary entity) at that same price plus an **administrative fee** calculated under 21 CFR § 1318.06(a).

4. **Until the transaction closes**, the manufacturer must store the crop in a facility to which **DEA maintains physical access**, and DEA may **inspect on demand**.

> **Open guidance gap.** § 1301.13(k)(6)(A) cross-references § 1318.06(a) for the administrative fee calculation, but neither the rule nor publicly available DEA materials specify the fee amount or calculation methodology (flat-per-harvest? percentage of nominal price? volume-based?). Treat this as a **watch-item pending DEA implementation guidance**; build SOPs that can absorb either a flat or percentage fee structure.

It is a paper transaction, but it requires: - A **nominal-price determination methodology** (defensible, consistent batch-to-batch — see watch-item § 9.10). - A **batch-record SOP** that triggers the buy/sell-back at harvest logging. - **Storage-area mapping** identifying the DEA-accessible facility. - **Facility-access protocols** for DEA inspectors (badging, escort, after-hours response).

Build the SOP and a mock paper transaction before your first post-registration harvest.

7.2 Cultivation-area specification (§ 1301.13(k)(6)(C))

The registration **must specify** the areas in which cultivation is permitted. New cultivation locations not on your registration cannot be brought into federal scope without a registration amendment. Build your facility expansion roadmap with this constraint in mind.

7.3 Records, reports, and order forms (§ 1301.13(k)(4))

DEA accepts **state-required records, reports, and forms to the maximum extent permissible**. In practice this means METRC and your state's reporting infrastructure carry most of the federal load. But: - Records must be **federally retrievable** during a § 1301.71 inspection — i.e., on-demand, not after a 30-day vendor request. - DEA may require additional federal-only records strictly necessary for treaty/statutory compliance (e.g., quota reconciliation, buy/sell-back batch records).

7.4 Inventory (§§ 1301.13(k)(4), 21 U.S.C. § 827)

- **Initial inventory** of all stocks of controlled substances on hand on the date federally registered activity begins.
- **Biennial inventory** every two years thereafter.

The state-licensed cultivator who has never run a federal initial inventory should expect this to be the first material federal-only documentation event after registration.

7.5 Statutory warning label (21 U.S.C. § 825(c); § 1301.13(k)(8))

The rule **exempts** state-medical registrants from Part 1302 labeling/packaging if they comply with state-law labeling/packaging — **with one exception**: every container's label must include the **§ 825(c) statutory warning** ("Caution: Federal law prohibits the transfer of this drug to any person other than the patient for

whom it was prescribed" — as adapted; verify final language with counsel). Add this to the existing state-required label artwork before federal scope begins.

7.6 Theft and loss reporting

Required for all DEA registrants under § 1301.74 / § 1301.76. State-medical registrants will typically have a parallel state-level reporting obligation; both must be triggered. Use **DEA Form 106** for the federal report.

7.7 Disposal (§ 1301.13(k)(9))

State-law-compliant disposal **is sufficient** for state-medical registrants — Part 1317 is not separately required. (Note: this state-law-substitute does **not** apply to FDA-approved drug products containing marijuana, which remain under Part 1317.)

7.8 Security (§ 1301.13(k)(10))

State-law-compliant physical security is sufficient. No separate § 1301.71–.76 federal security overlay is required, but expect DEA to inspect against state security regulations.

7.9 Auto-suspension on state-license loss (§ 1301.13(k)(3))

A DEA registration under § 1301.13(k) **automatically suspends** the moment the underlying state license is suspended, revoked, or expires. Renewal calendars must be tightly synchronized — a one-day state lapse is a federal lapse.

7.10 Federal scope ≤ state scope (§ 1301.13(k)(1) & (3))

Your registration cannot authorize anything your state license does not. State amendments (new locations, new substances, new activities) must be reflected in DEA registration amendments — and federal authority lags behind, not ahead of, state authority.

7.11 International export mechanics (21 CFR § 1312.30)

For the first time, state-licensed medical marijuana is **importable and exportable** under DEA permit. This is the single most consequential commercial expansion in the rule for operators with international demand. The mechanics are not fully spelled out by the rule and require careful unpacking.

What § 1312.30 actually does. The rule amends § 1312.30 to add the three new state-medical categories (FDA-approved drug products containing marijuana; marijuana extracts subject to a state medical license; naturally derived Δ9-THC subject to a state medical license) to the list of nonnarcotic Schedule III–V controlled substances **subject to the import/export permit requirement**. In other words: the *substance* is now eligible for import or export under DEA permit, where previously it was Schedule I and effectively non-exportable for state-medical operators.

Single-state origin — no interstate consolidation. Every export shipment must originate from a single state-licensed operation. A cultivator in State A cannot first move biomass to a hub in State B and ship from there — that intermediate move is interstate commerce in a still-Schedule-I-when-crossing-state-lines context.

Multi-state operators must operate **state-by-state** export workflows; there is no national export hub model that survives the rule. For an MSO with operations in five states pursuing export, this means five independent export pathways — five state licenses, five § 1301.13(k) registrations, five export permit streams.

The registration stack — a gray area. The rule does not expressly address whether a § 1301.13(k) operator needs an additional **Exporter** registration (per § 1301.13(e)(x), Form 225, $1,850/yr) to export, or whether the § 1301.13(k) registration alone is sufficient. The conservative working assumption is that the additional Exporter registration is required — DEA's import/export framework (Part 1312) operates as a separate registration scheme from manufacturing/distribution. Treat this as a **watch-item pending DEA implementing guidance**; build the application strategy to stack both registrations if export is in scope from day one.

Per-shipment DEA permits (Part 1312). Independent of registration, **each individual export shipment** requires its own DEA export permit issued under 21 CFR Part 1312. The permit is tied to a specific shipment, specific quantity, specific destination, and specific consignee. Permit lead times historically run 1–4 weeks for routine Schedule III–V exports; expect longer windows during the early implementation period for state-medical exports as DEA builds its processing muscle.

Destination-country compliance — independent of the U.S. side. The DEA export permit authorizes the *U.S. side* of the transaction. The destination country has its own regulatory framework that controls whether the product can enter and be sold: - **EU pharmacy markets** (Germany, UK, Czechia, Poland, Italy, etc.): **EU-GMP Part II + Annex 7** for the manufacture; **Annex 16 Qualified Person (QP)** certification for import release. - **Israel**: **IMC-GMP** (Israeli Medical Cannabis Agency standard, broadly aligned with EU-GMP Part II with IMC-specific overlays). - **Canada (partnered distribution)**: Health Canada **DEL** + **Good Production Practices**. - **Australia**: **TGA** with reference to PIC/S PE 009. - **Brazil**: **ANVISA** medical cannabis framework.

A state-licensed operator who is § 1301.13(k)-registered, has an additional Exporter registration, and holds a DEA export permit for a specific shipment **still cannot lawfully sell into Germany** unless their manufacturing site is qualified to EU-GMP. The U.S. permit is necessary but not sufficient.

Practical implication. International export is structurally available but operationally heavy. The realistic operator profiles in 2026: 1. **Single-state vertically integrated cultivator/processor** with EU-GMP qualification and an in-state export workflow, shipping direct to a foreign importer. 2. **Single-state export-of-record partner** — a § 1301.13(k)-registered distributor (or distributor-plus-exporter) that takes title from in-state manufacturers and serves as the export logistics partner. This is the "single-state export hub" thesis and is the most defensible distribution-only model in the rule's wake. 3. **MSO running parallel state export workflows** — high-overhead but the only model that lets a multi-state operator participate in export at all.

The "national cannabis exporter" model — aggregating product across states for a consolidated export — is structurally not possible under this rule. Track-3 broader rescheduling, if successful in 2027, may change that. For now, plan for state-by-state.

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8. Critical Calendar — Cultivator's Hard Dates

Date	Event	Consequence for cultivators
April 28, 2026	Final rule published; rescheduling effective; § 1301.13(k) live.	All downstream clocks start.
April 29, 2026 (9:00 AM ET)	DEA medical-marijuana **dispensary** portal opens (Form 224 only).	N/A for cultivators — file via standard DEA Diversion portal.
60 days after publication (on or about June 27, 2026 — the rule's "within 60 days of the publication" language anchored to FR publication on April 28).	**Expedited filing window closes.**	If filed within the window, the cultivator may **continue to operate under the state license during the pendency** of DEA review (§ 1301.13(k)(7)). DEA targets a six-month review for in-window filings. **Miss this and you lose the protected operating-continuity guarantee** — you cannot lawfully cultivate under federal law until DEA grants the registration.
June 29, 2026	DEA administrative hearing begins (Arlington, VA) for the broader Track-3 rescheduling (which would extend Schedule III to adult-use marijuana).	Watch closely. A favorable Track-3 outcome would dramatically expand the addressable medical-pathway equivalent.
July 15, 2026	Track-3 hearing must conclude no later than this date.	—
November 12, 2026	Federal hemp definition shifts to **"total THC including THCA"** under November 2025 legislation.	Distinct event, but cultivators with hemp operations (or hemp-derived intermediates in the supply chain) face a parallel reclassification risk.
2027 (estimated)	Possible final Track-3 rule, subject to litigation and Congressional Review Act.	—

> **Filing rule of thumb:** The arithmetic deadline is on or about **June 27, 2026** (60 days from FR publication). Do not anchor your internal target to the boundary. Submit no later than the **second week of June** to allow time to respond to DEA follow-up requests before the window closes. A complete and clean filing in early June is worth more than a maximally-aggressive filing on day 60.

9. Special Cases and Watch-Items

9.1 Dual-licensed operators (medical + adult-use)

Federal § 1301.13(k) covers **medical only**. If your state license combines both, register the medical scope and operationally segregate adult-use. Segregation must be defensible at: - Cultivation room / parcel level (engineering controls, badge zoning, HVAC). - METRC tag genealogy (medical vs. adult-use lineage). - Batch numbering and master-record architecture. - Disposal streams. - Chart of accounts (the § 280E apportionment is handled by Treasury/IRS, but the underlying cost data must support the apportionment).

9.2 States that designate medical/adult-use only at point of sale

Operators in states (e.g., Arizona) that designate medical vs. adult-use **only at the dispensary counter** likely **cannot** demonstrate that any specific cultivation lot is "subject to a state medical marijuana license" at the time of cultivation. Such operators may be **structurally ineligible** for § 1301.13(k) until the state regulatory model bifurcates upstream. Engage with the state regulator early.

9.3 Interstate commerce

Still illegal, even between two § 1301.13(k)-registered medical operators in two different states. The rule does **not** open the interstate medical lane. Only **international** import/export under DEA permit is newly available (§ 1312.30).

9.4 Synthetically derived THC

Δ-8, Δ-10, synthetic Δ-9 — **explicitly excluded** from the rescheduling. They remain Schedule I if they meet the CSA marijuana definition, or are otherwise federally controlled under analog or related authorities. Do not include them on a § 1301.13(k) application.

9.5 Hemp

Hemp under 7 U.S.C. § 1639*o* is **not** affected by this rule. But the **November 12, 2026** definition shift to total-THC-including-THCA may convert some currently-hemp lots into marijuana for federal purposes. Cultivators who operate parallel hemp lines need an internal cutover plan independent of the § 1301.13(k) work.

9.6 280E

The rule states qualifying state medical licensees are no longer subject to § 280E because § 280E applies only to Schedule I/II "trafficking." The Acting Attorney General **encouraged Treasury to consider retrospective relief** for past tax years. Treasury and IRS announced (April 23, 2026) they will issue guidance, including apportionment rules for dual-license operators. **No automatic refund.**

> **Caution on retroactive claims.** The rule's language is "encourages," not "mandates." It is **not** a Treasury safe-harbor and creates no enforceable right to refund. Practitioners should **specifically**

> **caution clients against filing amended returns for 2022–2025 solely on the basis of the April 2026 order** until either (a) Treasury issues formal transitional guidance, (b) the IRS publishes administrative procedures for retroactive § 280E claims, or (c) a Tax Court or other federal-court ruling supports the position. The IRS has historically litigated § 280E aggressively, including through *Northern California Small Business Assistants* and similar cases. Coordinate with cannabis tax counsel and a CPA before any retro-claim activity.

9.7 Banking

SBA and most federal banking restrictions on plant-touching cannabis are **unchanged**. SAFER Banking remains stalled. § 1301.13(k) registration does not automatically open federal banking lanes — but it does fortify the case for state-chartered cannabis-friendly institutions and for foreign banking partners in export-active jurisdictions.

9.8 Litigation and CRA risk

Smart Approaches to Marijuana (SAM) has announced an APA challenge. The rule contains an **express severability provision**, signaling DOJ anticipates partial challenges. A Congressional Review Act resolution could disapprove related rulemakings emerging from the Track-3 hearing. As of April 28, 2026, no injunction had issued. Build flexibility into compliance investments.

9.9 Research-supply transfers — security uplift question

Per § 1301.13(k)(10), a state-medical registrant's compliance with **state-law physical security** is sufficient for federal purposes — including, on the rule's face, for transfers to DEA-registered researchers. The rule states (page 23 of AG Order 6754-2026) that "*researchers who obtain marijuana or marijuana-derived products from a state licensee for use in scientific research shall incur no civil or criminal liability under the Controlled Substances Act solely by reason of having obtained such products from a state-licensed source rather than a separately DEA-registered bulk manufacturer, provided that the researcher is registered with the Administration to conduct research with marijuana under 21 CFR 1301.13 and the state licensee from whom the researcher obtained the marijuana held a valid federal registration at the time of the transfer.*"

The rule does **not** require the state licensee to upgrade to bulk-manufacturer-grade physical security (§ 1301.71/.72) at time of transfer. However, this point has been flagged in industry commentary as ambiguous. Conservative posture: maintain state-law security as the baseline; document the registration validity at time of transfer; expect DEA inspection of the transfer-out controls; track for DEA clarification guidance.

9.10 Nominal-price determination — the sham vs. tax-liability problem

The buy/sell-back requires a "nominal price" but the rule does not define it. Two failure modes exist: - **Too low:** the IRS or DEA could view the transaction as a sham — a paper exercise without economic substance — exposing the operator to recharacterization risk. Federal courts have struck down sham transactions in tax contexts. - **Too high:** the manufacturer recognizes a notional "sale" of inventory at a high value, potentially

triggering inventory-step-up tax liability or distorting state-tax positioning even though the resale at the same price plus fee leaves the operator economically whole.

Defensible methodology: anchor the nominal price to a documentable cost-of-goods or wholesale-comparable, applied **consistently** batch-to-batch, with a written rationale memo retained in the buy/sell-back batch record. Coordinate the methodology with cannabis tax counsel before first execution.

9.11 Internal transfers between medical and adult-use licenses

For dual-licensed operators, biomass that begins as "medical" (Schedule III under § 1301.13(k)) and is reassigned to "adult-use" inventory becomes Schedule I federal product the moment the reassignment occurs. The reverse direction is similarly fraught — adult-use biomass cannot lawfully be re-tagged as medical for federal-scope purposes. The rule does not provide express lot-conversion mechanics.

Conservative posture: **no internal transfers** between medical and adult-use lots. Plant lots, batch numbers, METRC tags, processing equipment, packaging components, and disposal streams must be designated as one or the other from cultivation onward. Build the segregation into the SOP architecture; treat any transfer event as a deviation requiring root-cause and federal-trafficking risk assessment until DEA issues guidance.

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10. Cultivator's Pre-Submission Checklist

A condensed action list. Use as a tracker.

Eligibility (§ 1) - [ ] State license is medical-scope and current - [ ] State license has no open enforcement action - [ ] Adult-use scope (if any) is operationally separable from medical scope - [ ] All officers/owners have clean controlled-substance histories (or remediation plan in hand)

Document pack (§ 4) - [ ] Business identity and entity documents assembled - [ ] State license copies (per location) collected - [ ] Liability disclosures drafted with context for any "yes" answer - [ ] Cultivation-area parcels / legal descriptions / floor plans compiled - [ ] Personnel access list (with disciplinary disclosures) compiled - [ ] Security profile per location documented - [ ] All twelve operational SOPs in place, dated, and signed off - [ ] Supplier and downstream-partner DEA numbers verified

Public-interest defense (§ 6) - [ ] Written § 823 factor-by-factor memo drafted - [ ] METRC reconciliation current, discrepancies remediated - [ ] Theft/loss log clean or fully explained - [ ] State enforcement actions resolved or documented

Application mechanics (§ 5) - [ ] Standard DEA Diversion portal access established (not the dispensary portal) - [ ] Drug codes selected (7362 ± 7353 ± 7386) - [ ] $3,699 fee staged for payment - [ ] Signature authority confirmed (officer or POA on file)

Operational readiness for post-registration (§ 7) - [ ] Buy/sell-back nominal-price methodology drafted - [ ] Buy/sell-back batch-record SOP in place - [ ] DEA-accessible storage facility identified - [ ] Initial-inventory plan ready for registration day - [ ] § 825(c) statutory warning added to label artwork - [ ] DEA

Form 106 theft/loss reporting workflow defined - [ ] State-license / DEA-registration renewal calendars synchronized

Calendar discipline (§ 8) - [ ] Application submitted by **mid-June 2026** (target before the second week of June; absolute boundary on or about June 27, 2026) - [ ] Internal owner assigned for follow-up to DEA RFIs during pendency - [ ] Six-month decision target tracked

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11. Authorities and Source Documents

Primary federal authorities

- **AG Order No. 6754-2026 / FR Doc. 2026-08176**, *Schedules of Controlled Substances: Rescheduling of Food and Drug Administration Approved Products Containing Marijuana From Schedule I to Schedule III; Corresponding Change to Permit Requirements* (final rule). Signed by Acting Attorney General Todd Blanche, April 22, 2026.
- **91 Fed. Reg. 22,714** (Tuesday, April 28, 2026) — Federal Register publication of AG Order No. 6754-2026. Effective April 28, 2026.
- **AG Order No. 6753-2026** — Notice of Hearing on Proposed Rulemaking (Track-3 broader rescheduling).
- **AG Order No. 6752-2026** — Withdrawal of the prior 2024 rescheduling proceedings (terminating the prior NPRM).

Statutory citations

- 21 U.S.C. § 811(d)(1) — treaty-compliance scheduling pathway
- 21 U.S.C. §§ 822, 823, 823(e)–(g) — registration and public-interest factors
- 21 U.S.C. § 825(c) — statutory warning label
- 21 U.S.C. § 827 — recordkeeping and inventory
- 21 U.S.C. § 829 — prescriptions
- 21 U.S.C. § 802(16) — definition of marijuana
- 7 U.S.C. § 1639*o* — definition of hemp

Regulatory citations

- 21 CFR § 1301.13(k) — new expedited registration pathway for state medical licensees
- 21 CFR § 1308.13(g)(2)–(4) — three new Schedule III drug-code entries (7362, 7353, 7386)
- 21 CFR § 1312.30 — addition of three new categories to Schedule III–V import/export permit list
- 21 CFR §§ 1318.02(b), 1318.04(b), 1318.06(a) — Single Convention nominal-price purchase/resale mechanism
- 21 CFR § 1300.01 — addition of "state medical marijuana license" definition

International authority

- Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol; in particular Articles 4, 19, 20, 21, 23, 28, 29, 30, 31, 33, 34.

DEA portals

- Standard DEA Diversion Control online registration portal (manufacturers + distributors): https://www.deadiversion.usdoj.gov/
- Medical-marijuana dispensary application portal (dispensers only): https://mmapplication.diversion.dea.gov/

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12. What This Primer Is and Is Not

This primer is a federal-licensing transition roadmap for state-licensed cannabis cultivators applying for DEA registration under the new 21 CFR § 1301.13(k) pathway. It walks through eligibility, document assembly, application mechanics, public-interest defense, post-registration operational obligations, and calendar discipline.

This primer is not a GMP overlay. It does not address 21 CFR Part 211 (cGMP for finished pharmaceuticals), 21 CFR Part 11 (electronic records / computer system validation), ICH Q1A(R2) stability, USP <1225>/<1226> analytical method validation, EU-GMP Part II / Annex 7, GACP, or the Qualified Person function. Those are distinct workstreams that map onto operators pursuing IND/NDA filings, clinical-trial supply, EU/Israeli export, or pharma-partnership contracts. Intrepid Scientific delivers those overlays separately — see the companion piece **"The Pharmaceutical Era: A Strategic Roadmap for Cannabis Manufacturing After Rescheduling"** for the integrated build framework.

This primer is not legal or tax advice. Every cultivator is encouraged to confirm liability disclosures, public-interest factor positioning, 280E posture, and any litigation-driven contingencies with qualified counsel and a cannabis CPA before filing.

Next Steps for Your Operation

If you are reading this and your facility is not yet on the federal-pathway trajectory, **mid-June is your filing-readiness target.** That leaves a small number of weeks to assemble the document pack, write the public-interest defense memo, and submit a clean Form 225.

Intrepid Scientific offers two engagement options for this moment:

1. Federal Pathway Readiness Diagnostic — $4,000 fixed fee. A two-day diagnostic: one day on-site, one day off-site. Delivers a gap assessment against 21 CFR § 1301.13(k) Public Interest factors, a prioritized remediation roadmap, and a binding scope recommendation for any follow-on Part 211 / EU GMP build. If

the diagnostic shows your file is ready to submit as-is, we tell you that and you save a year of unnecessary consulting.

2. Filing Support Engagement — quote-based. For operators who need hands-on help assembling the document pack, drafting the public-interest defense memo, building the buy/sell-back nominal-price methodology and SOP, and standing up the federal-only documentation infrastructure (initial inventory, § 825(c) label addition, DEA Form 106 workflow) before submission. Phased and decision-gated like all our project engagements.

[Talk to us about a Readiness Diagnostic →] *(contact-form link)*

[Read the strategic companion piece — "The Pharmaceutical Era" →] *(insights link)*

About the Author

Andrew Samann is a Cofounder of Intrepid Scientific. Recognized as a Processing Pro on The Cannabis Scientist's Power List for 2021 and 2022, Andrew has led over 100 GMP and quality-system engagements across North America, South America, and the European Union — including international compliance work against FDA, EU GMP, EMA, Australian TGO, and ICH guidelines. He led the ASTM D37.02 Quality Management Systems Subcommittee for Cannabis, has certified multiple Canadian cannabis Licensed Producers, and is also Founder & CEO of Orion GMP Solutions.

About Intrepid Scientific

Intrepid Scientific is an independent scientific consulting firm offering ISO/IEC 17025 lab accreditation readiness, GMP and cGMP compliance, analytical method development and validation, microbiology and environmental monitoring, expert witness, and Federal Pathway / Schedule III advisory across cannabis, hemp, food and beverage, pharmaceutical, and dietary-supplement industries. Senior scientists. Direct engagement.

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Learn more at intrepidscientific.com.