ORAL ARGUMENT NOT YET SCHEDULED

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

G.P.M.II, LLC; MLH EXPLORATIONS LLC; TRI-MOUNTAIN PURE, LLC; and STORY OF PA CR, LLC, *Petitioners*, v. DRUG ENFORCEMENT ADMINISTRATION; TERRANCE C. COLE, in his official capacity as ADMINISTRATOR OF THE DRUG ENFORCEMENT ADMINISTRATION; UNITED STATES DEPARTMENT OF JUSTICE; and TODD BLANCHE, in his official capacity as UNITED STATES ATTORNEY GENERAL, *Respondents*.	No. 26-1325 Consolidated with Case No. 26-1324

EMERGENCY MOTION FOR STAY OF AGENCY ACTION PENDING REVIEW AND FOR IMMEDIATE ADMINISTRATIVE STAY

CERTIFICATE OF COMPLIANCE WITH CIRCUIT RULE 18(a) AND FEDERAL RULE OF APPELLATE PROCEDURE 18

The motion complies with Circuit Rule 18 and Federal Rule of Appellate Procedure 18. On November 12, 2026, Petitioners urged the Drug Enforcement Administration ("DEA") to stay the effective date of the October 30, 2026 guidance at issue pending judicial review. Petitioners requested a response from DEA by November 17, 2026, and advised that, absent a response by that date, Petitioners would seek judicial review. DEA did not respond to Petitioners' request, which Petitioners must treat as a constructive denial due to the impending deadline. Because it would be impracticable to await a decision from DEA, Petitioners have complied with Circuit Rule 18 and Federal Rule of Appellate Procedure 18. On November 19, 2026, counsel for Petitioners notified counsel for Respondents by e-mail that they planned to file this Motion, and followed up that e-mail with calls to the DOJ's Civil Appellate Division and the General Civil Division at the US Attorney's Office for the District of Columbia.

Counsel for respondents responded via e-mail on November 19, 2026, that the respondents "oppose an injunction pending appeal and an immediate injunction pending review of the motion."

CERTIFICATE AS TO PARTIES, RULINGS AND RELATED CASES PURSUANT TO CIRCUIT RULE 28(a)(1)

A. Parties and Amici

Petitioners are G.P.M.II, LLC, MLH Explorations LLC, Tri-Mountain Pure, LLC, and Story of PA CR, LLC (collectively "Petitioners"). Respondents are the Drug Enforcement Administration, Terrance C. Cole, in his official capacity as Administrator of the Drug Enforcement Administration, Department of Justice, and Todd Blanche, in his official capacity as Attorney General (collectively "Respondents").

The ruling under review was not issued in an adjudicatory or rulemaking proceeding in which other persons participated. Counsel is not aware of any other persons or entities that participated in proceedings before DEA, and no intervenors or amici have appeared in this Court as of this filing.

B. Ruling Under Review

The ruling under review is the document tilted "DEA Medical Marijuana Timely Applicant Information," which was issued by the DEA on October 30, 2026. It is attached as Exhibit K to the Declaration of Michael McQueeny. The document was not published in the Federal Register.

C. Related Cases

This case has been consolidated with *Standard Wellness Utah, LLC, et al., v. Drug Enforcement Admin., et al.*, Case No. 26-1324 (D.C. Cir. 2026). Other than

that case, counsel is not aware of any related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

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INTRODUCTION

Petitioners are four vertically integrated businesses operating in good standing under Pennsylvania's medical marijuana program. Each has applied to federally register its dispensaries and manufacturing facilities under the Attorney General's April 2026 order rescheduling medical marijuana as a Schedule III controlled substance. Petitioners applied early—within 60 days of the rescheduling order—to register their dispensaries. They did not apply to register their manufacturing operations due to inconsistent and confusing direction from DEA. As a result, under new guidance issued by DEA on October 30, 2026, Petitioners' manufacturing divisions will be barred from supplying any entity that is federally registered or that applied for registration during the 60-day window—including their *own* dispensaries—as of November 29, 2026. But the Guidance is procedurally deficient, contrary to law, and arbitrary and capricious; its offending provisions should be immediately stayed.

In April 2026, the Attorney General moved medical marijuana from Schedule I to Schedule III of the Controlled Substances Act ("CSA"). As part of that action, the Attorney General provided that state-licensed operators who applied for federal registration within 60 days of the rule's publication could continue operating "in conformity with a state-issued license during the pendency of the application." 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, 91 Fed. Reg. 22,714, 22,722 (Apr. 28, 2026) (codified at 21 C.F.R. §1301.13(k)(7)).

On October 30, 2026, however, DEA published online guidance (the "Guidance") contradicting that provision. Ex.K.[1] As of November 29, 2026, the Guidance advises, early applicants may do business *only* with other early applicants and existing registrants (the "counterparty restriction")—on pain of severe penalty. Ex.K ¶¶5-8.

Despite the Attorney General's stated aim of "the least disruption for patients and existing state systems," 91 Fed. Reg. at 22,720, the Guidance will generate massive disruption by forcing early applicants (like Petitioners) to overhaul supply chains in a few short weeks, and shutting down facilities (like Petitioners' manufacturing divisions) that lack early-applicant status. Patients who rely on medical marijuana to treat chronic and debilitating conditions will bear the cost.

Petitioners move under 5 U.S.C. §705 and Federal Rule of Appellate Procedure 18 for a stay of the Guidance's unlawful provisions pending the Court's review. Petitioners further request an immediate administrative stay while the

[1] "Ex." refers to exhibits to the McQueeny Declaration, filed herewith.

Court considers Petitioners' request for stay pending review. A stay is warranted: Petitioners are likely to succeed on the merits because the Guidance is a legislative rule issued without notice or comment, and is contrary to law and arbitrary and capricious; Petitioners will be irreparably injured absent an immediate stay; and a stay will serve the public interest and cause no harm to the government.

BACKGROUND

A. The Rescheduling Order

On April 28, 2026, DEA published AG Order No. 6754-2026 (the "Order"). 91 Fed. Reg. at 22,714. The Order moved FDA-approved drug products containing marijuana, and marijuana subject to a state-issued medical-marijuana license, from Schedule I to Schedule III of the CSA. *Id.* at 22,718.

The Order required DEA to "establish an expedited review process for entities holding state medical marijuana licenses who seek [federal] registration." 21 C.F.R. §1301.13(k). It also instructed that any entity that applied for federal registration within 60 days of the Order's publication—what the Order called an "early applicant[]"—could continue to operate while its application is pending (the "interim period"), so long as it does so "in conformity with a state-issued license." *Id.* §1301.13(k)(7); *see* 91 Fed. Reg. at 22,720-22.

The Attorney General grounded the Order in express findings about state medical-marijuana regimes. It recognized that state licensing regimes "have

developed robust infrastructure for preventing diversion, ensuring product safety, maintaining records, and conducting facility inspections—functions that fulfill the objectives of federal registration and recordkeeping requirements." *Id.* at 22,720. And it found that "state systems … demonstrate a sustained capacity to achieve the public-interest objectives that underlie the CSA's registration framework, including protecting public health and safety and preventing the diversion of controlled substances." *Id.* Based on those findings, the Order stated that its implementing regulations were "designed to reduce regulatory burden on compliant state-licensed entities" and to bring such entities into the federal system with "the least disruption for patients and existing state systems." *Id.*

The regulations reinforce these goals. They presume that federal registration of state-licensed medical-marijuana operators is in the public interest, 21 C.F.R. §1301.13(k), and tie continued federal registration to continued state licensure, *id.* §1301.13(k)(3). The regulations also exempt state-licensed operators from federal "labeling, packaging, and sealing requirements," *id.* §1301.13(k)(8), and recognize that state-licensed operators have "sufficient physical-security requirements," *id.* §1301.13(k)(10).

The Attorney General concluded that 21 U.S.C. §811(d)(1) exempted the Order from notice-and-comment rulemaking because the United States is obligated

to control marijuana under the Single Convention on Narcotic Drugs. 91 Fed. Reg. at 22,720-21.

B. The 60-Day Period and DEA's Conflicting Guidance

The following day, DEA launched an online "Medical Marijuana Dispensary Registration Portal" through which medical-marijuana dispensaries could apply for DEA registration (the "Dispensary Application"). Exs.A, B. The agency publicly announced the Dispensary Application, and advised dispensary applicants to use it. *See* Exs.A, G. The Dispensary Application required detailed information, including: state-license information; the applicant's suppliers; the applicant's standard operating procedures for storage, security, dispensing and delivery, destruction, and recordkeeping; and the name, title, date of birth, social-security number, federal and state authorizations, and disciplinary and criminal history of every individual handling medical marijuana. Ex.B. Each Petitioner used the Dispensary Application to register during the 60-day period. Sheahan Decl. ¶14; Washington Decl. ¶15; Reilly Decl. ¶15; Waggoner Decl. ¶17.

DEA did not contemporaneously launch a similar application portal for manufacturers. DEA maintains a general registration application for manufacturers under the CSA, Ex.C, but it is a generic form that predates the Order. McQueeny Decl. ¶4. It requires applicants to provide only standard

business and contact information, and to select from a dropdown menu of drug codes the substance(s) the applicant intends to handle. Ex.D.

In early May 2026, the following notice appeared on DEA's application webpage under "Medical Marijuana Manufacturer":

> If you have already submitted your application to register for a DEA Registration as a manufacturer and/or distributor to handle Schedule III medical marijuana … pursuant to the AG Order No. 6754-2026, we will be in contact with you shortly to continue processing your application – there is no need to reapply.
>
> Those interested in applying for a DEA registration to handle Schedule III medical marijuana pursuant to the AG Order No. 6754-2026, ***may*** do so utilizing DEA's current Form 225 application. When applying as a Manufacturer, Bulk Manufacturer (grower/cultivator), Analytical Lab, or Distributor, you must only select the following applicable medical marijuana drug codes 7362, 7353, and/or 7386. ***Do not select drug codes that are not related to medical marijuana.*** We will be in contact with you regarding these applications.
>
> In ***the coming weeks***, an updated 'Medical Marijuana Manufacturer', 'Medical Marijuana Bulk Manufacturer (grower/cultivator)', 'Medical Marijuana Analytical Lab', and 'Medical Marijuana Distributor' application will be available specifically for handling Schedule III medical marijuana and posted on DEA Diversion's Registration page.

Ex.E (emphases added). DEA's application webpage warns that "[a]pplying for a registration with the wrong Business Category/Activity will cause either delay in processing your application or the withdrawal of your application." Ex.C.

Media coverage reflected industry confusion surrounding DEA's "coming soon" notice. As one article explained, "it was unclear if a separate registration portal would open for other medical cannabis license types, such as manufacturers,

or if they were expected to use the DEA's [generic form] to complete the process." Ex.H. The generic form required significantly less information than the Dispensary Application. *See* Exs.B, D; Sheahan Decl. ¶12b; Washington Decl. ¶13b; Reilly Decl. ¶13b; Waggoner Decl. ¶15b. And the generic bulk-manufacturing form included no medical-marijuana drug codes, which—given DEA's instruction "not [to] select drug codes that are not related to medical marijuana"—signaled that the form was not meant for medical-marijuana manufacturers. *See* Exs.C, D; McQueeny Decl. ¶8a.

Aside from DEA's notice, the agency never issued guidance to medical-marijuana manufacturers on the registration process. And DEA field agents and help-line operators expressly advised individual manufacturers to wait for the medical-marijuana-specific forms. Waggoner Decl. ¶¶11, 15a; Reilly Decl. ¶18. The 60-day window ended on June 26, 2026, with the promised applications still unavailable and the "coming soon" notice still posted. *See, e.g.*, Reilly Decl. ¶16. On or about October 5, 2026, DEA finally made available a dedicated application for medical-marijuana manufacturers. McQueeny Decl. ¶7; Ex.F.

C. The October 30 Guidance

On October 30, 2026, DEA issued the Guidance for early applicants—which DEA now calls "Timely Applicants." Ex.K ¶2. The Guidance defines "Timely Applicants" as entities that submitted a completed application for registration by

June 26, 2026. *Id.* DEA also posted a list of Timely Applicants (the "Timely Applicant List"). Ex.L. The only manufacturers appearing on the list are those that applied using the generic form. *Id.*

The Guidance "addresses the permissible activities that applicants for DEA registration … may continue to engage in while their DEA applications remain pending." *Id*. at p.1. Consistent with the Order, paragraph 1 of the Guidance advises that a Timely Applicant "can dispense, manufacture, or distribute schedule III medical marijuana … pursuant to its state medical marijuana license during the pendency of the application." Ex.K ¶1; *see also id.* ¶¶2-4. But subsequent paragraphs deviate from the Order. In particular, and for the first time, the Guidance proclaims that Timely Applicants and registrants "may not lawfully engage in any schedule III medical marijuana activities with entities that did not complete an application" by June 26, 2026, "until those entities become DEA registrants." *Id.* ¶7; *see also id.* ¶¶5-6. Doing so, the Guidance warns, "could be potential grounds for denial of a Timely Applicant's application or revocation of a certificate of registration." *Id.* ¶8. The Guidance therefore directs Timely Applicants and registrants to "take adequate steps to confirm the status of all entities with which they will conduct schedule III medical marijuana activities," and lists "minimum" due-diligence requirements. *Id.* ¶8. The Guidance further

instructs Timely Applicants to "establish compliant supply chains no later than November 29, 2026." *Id.* ¶11.

Despite these new restrictions and threatened sanctions, the Guidance's final paragraph asserts that the document carries neither the force nor effect of law. *Id.* at p.4.

D. Petitioners and Their DEA Registration Applications

Petitioners are vertically integrated medical-marijuana businesses that cultivate, process, and dispense medical marijuana under licenses issued by the Pennsylvania Department of Health ("DOH"). Sheahan Decl. ¶3-4; Washington Decl. ¶3-4; Reilly Decl. ¶3-4; Waggoner Decl. ¶3-4. Each Petitioner operates at least one dispensary and a grower/processor facility that supplies its own dispensaries, and over one hundred third-party licensed dispensaries across the Commonwealth. Sheahan Decl. ¶3; Washington Decl. ¶3; Reilly Decl. ¶3; Waggoner Decl. ¶3. Pursuant to their Pennsylvania-issued licenses, Petitioners are authorized to do business with any other Pennsylvania medical-marijuana operator in good standing with DOH. *See* 35 Pa. Stat. §10231.616(6)-(7); 28 Pa. Code §1151a.35(a). Together, Petitioners serve tens of thousands of patients each month. Sheahan Decl. ¶3; Washington Decl. ¶3; Reilly Decl. ¶3; Waggoner Decl. ¶3.

Petitioners' Pennsylvania licenses subject them to exacting anti-diversion controls. Pennsylvania law requires that Petitioners manage daily electronic seed-to-sale tracking systems directly accessible to DOH, 35 Pa. Stat. §10231.701(a); maintain surveillance systems subject to regular inspection and 180-day recording-retention requirements, *id.* §§10231.702(b)(2), 10231.802(a)(1.1); 28 Pa. Code §§1151a.26(b)(1), 1161a.31(a)(4), (b)(1); notify DOH daily of delivery routes, 28 Pa. Code §§1151a.35(g); and immediately report any loss, 28 Pa. Code §1151a.35(f)-(g).

As the Order recognized, 91 Fed. Reg. at 22,716, 22,720, these requirements meet or exceed federal controls governing DEA registrants. *Compare, e.g.*, 35 Pa. Stat. §§10231.301(a)(13), 10231.701(a), *and* 28 Pa. Code §§1151a.30(b)-(c), 1161a.32(b)-(c), *with* 21 C.F.R. §§1304.04, 1304.11, 1304.21-.22; *and compare* 35 Pa. Stat. §10231.606(a)(2), *and* 28 Pa. Code §§1151a.26(b)(1), 1151a.35(f), *with* 21 C.F.R. §§1301.71-.72, 1301.74(c), 1301.76(b).

Post-Order, Petitioners moved promptly to register with DEA. Each applied to register its dispensary operations using DEA's Dispensary Application during the 60-day window, and DEA lists each as a "Timely Dispenser Applicant." Ex.L. DEA also subjected Petitioners' dispensaries to rigorous review, requesting detailed information and conducting on-site inspections. Washington Decl. ¶17; Reilly Decl. ¶17; Waggoner Decl. ¶19.

Petitioners did not submit applications for their manufacturing operations within the 60-day period. Relying on DEA's assurance that a medical-marijuana-specific manufacturer application was forthcoming, Ex.E, and mindful of DEA's warning against filing under the wrong application, Ex.C, Petitioners applied to register their manufacturing facilities after DEA released the manufacturer-specific application on October 5, 2026. Sheahan Decl. ¶19; Washington Decl. ¶16; Reilly Decl. ¶22; Waggoner Decl. ¶20.

Given this background and the Order's text, *see supra* pp. 3-5, Petitioners were stunned by the Guidance's counterparty restriction. The impact was immediate. Petitioners' dispensaries (which, again, have "Timely Applicant" status) were abruptly cut off from their primary suppliers—Petitioners' manufacturing divisions—forcing them to search for alternative supply from *competitor* manufacturers. And Petitioners' manufacturing divisions began to receive calls from customers demanding proof of "Timely Applicant" status, canceling orders, and advising that they could no longer purchase from Petitioners. Washington Decl. ¶22; Reilly Decl. ¶23; Waggoner Decl. ¶23.

JURISDICTION AND LEGAL STANDARD

This Court has jurisdiction under 21 U.S.C. §877, which authorizes this Court to review "'[a]ll final determinations, findings, and conclusions' of the DEA applying the CSA." *John Doe, Inc. v. DEA*, 484 F.3d 561, 568 (D.C. Cir. 2007)

(quoting 21 U.S.C. §877). DEA published the Guidance under authority delegated by the Attorney General, 21 U.S.C. §871(a)-(b), and Petitioners filed this petition within the 30 days §877 allows.

The Guidance is a "final determination[]." *John Doe*, 484 F.3d at 565-66 & n.4 (applying *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997), under §877). It states DEA's definitive position as to which entities qualify as "Timely Applicants" and with whom they may deal, and it carries legal consequences: dealing with entities not on the "Timely Applicant" list could result in DEA denying or revoking federal registration, and Timely Applicants must establish "compliant" supply chains by November 29, 2026. *See Barrick Goldstrike Mines Inc. v. Browner*, 215 F.3d 45, 50 (D.C. Cir. 2000) (guidance was final agency action where "[l]egal consequences flow[ed] from the position expressed" and party had to comply "unless it wishe[d] to risk an enforcement action").

Courts must set aside agency action taken "without observance of procedure required by law," 5 U.S.C. §706(2)(D), including legislative rulemaking carried out without the notice-and-comment protections §553 requires. *Id.* §553(b)-(c); *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015). When reviewing agency action, courts must "hold unlawful and set aside" agency action that is "arbitrary, capricious," or "otherwise not in accordance with law." 5 U.S.C. §706(2)(A).

During review, courts may also stay "the effective date of an agency action or … preserve status or rights," *id.* §705; *see* Fed. R. App. P. 18.

Whether a stay is warranted turns on four factors: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Nken v. Holder*, 556 U.S. 418, 434 (2009).

ARGUMENT

I. Petitioners Are Likely to Succeed on the Merits.

A. DEA Failed to Adhere to the APA's Procedural Requirements.

The APA requires that federal agencies engage in "notice-and-comment rulemaking" before promulgating legislative rules. *Perez*, 575 U.S. at 96. This "ensure[s] fairness to affected parties" and that "agency regulations are tested … [by] diverse public comment." *Int'l Union, UMW v. MSHA*, 407 F.3d 1250, 1259 (D.C. Cir. 2005). The "notice-and-comment requirement" does not apply to "interpretative" rules or general policy statements that lack the "force and effect of law." *City of Billings v. Transp. Sec. Admin.*, 153 F.4th 46, 52 (D.C. Cir. 2025). But "an agency may not escape the notice and comment requirements by labeling a major substantive legal addition to a rule a mere interpretation." *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1024 (D.C. Cir. 2000) (cleaned up). Courts

instead look to the document's substance and effect, asking whether it "spells out a duty [not] fairly encompassed within the regulation that the interpretation purports to construe." *Air Transp. Ass'n of Am. v. FAA*, 291 F.3d 49, 55-56 (D.C. Cir. 2002) (quotation omitted).

The Guidance's counterparty restriction imposes three new duties: a bar on dealing with entities that are not Timely Applicants or registrants, a due-diligence mandate, and a fixed compliance deadline. Ex.K ¶¶5-8, 11. None is fairly encompassed within 21 C.F.R. §1301.13.

First, the Guidance bars Timely Applicants from doing business with entities that did not apply during the 60-day window until those entities secure federal registration. Ex.K ¶¶5-7. But the only provision of §1301.13 that addresses the application period is subparagraph (k)(7), and it expressly authorizes "any applicant that submits an application within 60 days of the publication of [the] rule" to continue to manufacture, distribute, or dispense medical-marijuana products "in conformity with" its state license, "[n]otwithstanding paragraph (a)." 21 C.F.R. §1301.13(k)(7). Paragraph (a) provides that "[n]o person required to be registered shall engage in any activity for which registration is required until the application for registration is granted[.]" 21 C.F.R. §1301.13(a).

The provisions thus set out a distinct pathway, with a distinct limitation, for early applicants. While paragraph (a) bars activity that requires registration until

registration is granted, subparagraph (k)(7) lifts that bar and instructs that, instead of being subject to paragraph (a), applicants that submitted a federal-registration application by June 26, 2026, may engage in schedule III medical-marijuana activities while their applications are pending, so long as those activities are carried out "*in conformity with a state-issued license*." 21 C.F.R. §1301.13(k)(7) (emphasis added). Under Petitioners' Pennsylvania-issued licenses, they may do business with other Pennsylvania-licensed medical-marijuana operators. *See* 35 Pa. Stat. §10231.616(6)-(7). In other words, under Petitioners' state licenses—and therefore under the Order—Petitioners' dispensaries (and any other early applicant) may continue doing business with Petitioners' manufacturing divisions. The Guidance alone bars such dealings.

True, the regulation contains counterparty limits in subparagraph (k)(1). *See* 21 C.F.R. §1301.13(k)(1)(i)-(iii) (limiting registered manufacturers and distributors to dealing with specified registrants, and registered dispensers to dispensing to state-authorized patients). But subparagraph (k)(1) concerns only *registered* entities; it does not apply to early applicants—which, by definition, are not yet registered, *see* 21 C.F.R. §1301.13(k)(1)(i)-(iii). Only subparagraph (k)(7) addresses applicants, and as explained, it provides distinct benefits and restrictions for those applicants. *See supra* p.15.

Perhaps for that reason, the Guidance does not purport to interpret or implement subparagraph (k)(1). Instead, it roots its counterparty restriction in "the prohibition under 21 CFR 1301.13***(a)***." Ex.K ¶7 (emphasis added). But paragraph (a) is likewise no help to DEA, for as explained, subparagraph (k)(7) *removes* that restriction as to early medical-marijuana applicants, 21 C.F.R. §1301.13(k)(7) ("Notwithstanding paragraph (a) …."), and *replaces* it with another during the pendency of applications submitted during the 60-day period: "conformity with a state-issued license," *id.*

Were that not enough, the Guidance also backs its novel counterparty restriction with sanctions—another indication of legislative rulemaking. It states that continuing to do business with any non-Timely Applicant could be grounds for "denial of a Timely Applicant's application or revocation of a certificate of registration." Ex.K ¶8. These penalties evince legislative rulemaking by "lead[ing] private parties … to believe" DEA will sanction them "unless they comply with the terms of the document"—making the document "for all practical purposes 'binding.'" *Appalachian Power*, 208 F.3d at 1021.

Second, the Guidance directs "Timely Applicants" and registrants to "confirm the status of all entities with which they will conduct schedule III medical marijuana activities" by November 29, 2026, and lists "minimum" due-diligence steps, including obtaining each counterparty's DEA application confirmation or

certificate of registration. Ex.K ¶¶8, 11. Neither §1301.13 nor Pennsylvania's licensing regime imposes such an obligation. Yet the Guidance warns that Timely Applicants and registrants risk their own applications and registrations, respectively, by transacting with an unverified counterparty. Ex.K ¶8. It thus "spells out a duty" that is not "fairly encompassed within the regulation." *Air Transp. Ass'n*, 291 F.3d at 55-56; *see Mendoza v. Perez*, 754 F.3d 1002, 1021-24 (D.C. Cir. 2014) (rule describing specific steps with which parties were required to comply was legislative in nature). That is legislative, not interpretive, rulemaking.

Third, the Guidance sets a hard November 29, 2026, compliance deadline for the new duties it establishes. Ex.K ¶11. Such a deadline reinforces the legislative nature of the Guidance because, without it, DEA would have no "legislative basis for enforcement action" against Timely Applicants whose business dealings conform with their state licenses, *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993).

Because the counterparty restriction is a legislative rule, DEA was obligated to proceed through notice-and-comment rulemaking. This is so even though the Order itself did not require notice-and-comment procedures. *See supra* pp. 3-5. The Guidance neither implicates the United States' treaty obligations nor merely interprets the April 2026 rescheduling order. DEA's failure to observe the APA's

notice-and-comment protections therefore requires that the counterparty restriction be set aside. *See* 5 U.S.C. §706(2)(D).

B. The Counterparty Restriction Is Arbitrary and Capricious and Contrary to Law.

1. The Counterparty Restriction Is Inconsistent with §1301.13's Text.

Agency action that conflicts with the agency's own regulations is "arbitrary, capricious," and "not in accordance with law." 5 U.S.C. §706(2)(A); *see Alon Refin. Krotz Springs, Inc. v. EPA*, 172 F.4th 12, 14 (D.C. Cir. 2026) (vacating agency "interpretation of its own regulation [because it was] contrary to the [regulation's] plain text"); *Nat'l Env't Dev. Ass'n's Clean Air Project v. EPA*, 752 F.3d 999, 1009-10 (D.C. Cir. 2014) (same, on principle that "[an] agency is not free to ignore or violate its regulations").

The counterparty restriction is such an action. As explained, subparagraph (k)(7) permits early applicants to continue operating during the pendency of their federal applications so long as they act "in conformity with a state-issued license." By its terms, this text permits Petitioners' dispensaries to purchase from any Pennsylvania-licensed manufacturer—including Petitioners' own manufacturing divisions. *See supra* p. 8. It also authorizes any other "Timely Applicant" dispensary to purchase from Petitioners' manufacturing arms. By barring Timely Applicants from dealing with entities that filed federal registration applications

after the 60-day window, the counterparty restriction negates the authority (k)(7) grants, making the Guidance arbitrary and capricious and "not in accordance with law." *See Alon*, 172 F.4th at 17-19.

Petitioners could not, therefore, have anticipated the counterparty restriction and its sanctions. For this reason, too, the Guidance is contrary to law, as an agency may not penalize a regulated party without first providing "adequate notice." *See Satellite Broadcasting Co. v. FCC*, 824 F.2d 1, 2 (D.C. Cir. 1987). Notice is adequate "[i]f, by reviewing the regulations and other public statements issued by the agency, a regulated party acting in good faith would be able to identify, with 'ascertainable certainty,' the standards" it must follow and the consequences of noncompliance. *Gen. Elec. Co. v. EPA*, 53 F.3d 1324, 1329 (D.C. Cir. 1995) (citation omitted). But nothing in the Order or DEA's public statements indicated that a "timely" medical-marijuana applicant would be restricted to doing business with other "timely" applicants during the interim period—nor that "non-timely" applicants would be cut out of the market until registered. *See supra* pp. 3-5. Particularly where, as here, "sanctions are drastic," *see infra* pp. 21-22, "'elementary fairness compels clarity' in the statements and regulations setting forth the [rules] with which the agency expects [regulated parties] to comply." *Gen. Elec. Co.*, 53 F.3d at 1329 (quoting *Radio Athens, Inc. v. FCC*, 401 F.2d 398, 404 (D.C. Cir. 1968)).

2. DEA Failed to Provide a Reasoned Explanation for the Counterparty Restriction.

The counterparty restriction is also arbitrary and capricious because DEA failed to "articulate a satisfactory explanation" for establishing it. *Air All. Houston v. EPA*, 906 F.3d 1049, 1066 (D.C. Cir. 2018) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Agency action is arbitrary and capricious when it contradicts the agency's prior findings without adequate explanation, *see FCC v. Fox Television Stations*, 556 U.S. 502, 515-16 (2009), or "entirely fail[s] to consider an important aspect of the problem," *State Farm*, 463 U.S. at 43. The counterparty restriction does both.

First, the Order rests on a key finding: state licensing regimes fulfill the objectives of "federal registration and recordkeeping requirements" and have demonstrated the capacity to protect "public health and safety" and prevent the "diversion of controlled substances." *See supra* pp. 3-5. The regulation therefore presumes that federal registration of state-licensed medical-marijuana operators is in the public interest. 21 C.F.R. §1301.13(k).

The Guidance disregards these findings and purports to establish prohibitions and penalties that defy them. Under the counterparty restriction, state licensure is irrelevant during the interim period unless it is paired with an application submitted prior to June 26, 2026. It also threatens to cut state-licensed operators like Petitioners' manufacturing divisions—which are subject to the same

federally endorsed state oversight as "Timely Applicants"—out of the market. Ex.K ¶8.

DEA fails even to acknowledge that the Guidance deviates from the Order, let alone to explain why it now deems state licensure regimes inadequate. But an agency must "provide 'a reasoned explanation … for disregarding facts and circumstances that underlay [its] prior policy.'" *Air All. Houston*, 906 F.3d at 1066 (quoting *Fox*, 556 U.S. at 515). Failure to do so is arbitrary and capricious.

Second, DEA ignored an "important aspect of the problem" it had previously acknowledged. *State Farm*, 463 U.S. at 43. The Order was "designed to reduce regulatory burden on compliant state-licensed entities" and to bring state-licensed medical marijuana operators into the federal system with "the least disruption for patients and existing state systems." 91 Fed. Reg. at 22,720. Yet the Guidance failed to acknowledge these objectives, explain how the counterparty restriction is consistent with them, or consider how the new restrictions and sanctions might upset state operations or patient wellbeing.

DEA also ignored the role its conflicting instructions played in the "non-timely" applications of many medical-marijuana manufacturers. Petitioners and other manufacturers reasonably understood that DEA would launch a manufacturer-specific registration process within the 60-day window, *see* Sheahan Decl. ¶11; Washington Decl. ¶12; Reilly Decl. ¶12; Waggoner Decl. ¶¶11, 14, and

in any event, were advised by DEA's agents to forgo the generic application form and await the manufacturer-specific application, *see supra* 5-7. Those parties imminently face irreparable harm despite good-faith efforts to comply with DEA's instructions. *See infra* pp. 22-25.

II. Petitioners Will Suffer Irreparable Harm Absent a Stay.

Unless stayed, the counterparty restriction will take effect in ten days, November 29, 2026. On that date, Petitioners' manufacturing divisions will no longer be able to supply Petitioners' dispensaries or any others on the "Timely Applicant" list. The results will be devastating—for Petitioners' businesses and reputations, for the many individuals they employ, and for the countless patients they serve.

A. The Guidance Threatens the Existence of Petitioners' Businesses.

A petitioner faces irreparable harm from an administrative action where "it faces a grave risk of being forced out of business before full [agency] review, rendering any opportunity for later review at best inadequate and, at worst, moot." *Alpine Sec. Corp. v. Fin. Indus. Regul. Auth.*, 121 F.4th 1314, 1329 (D.C. Cir. 2024). Likewise, "financial injury can be irreparable where no adequate compensatory or other corrective relief will be available at a later date." *In re NTE Conn., LLC*, 26 F.4th 980, 990 (D.C. Cir. 2022) (cleaned up). That is the harm Petitioners face here.

The counterparty restriction will upend Petitioners' businesses. Their manufacturing arms stand to lose hundreds of thousands of dollars in monthly revenue from third-party-dispensary sales alone. Waggoner Decl. ¶24; Washington Decl. ¶23; Reilly Decl. ¶24. And Petitioners' dispensaries will be forced to buy from competitor manufacturers (if they are even able to locate sufficient supply)—or cease operations. *See* Sheahan Decl. ¶21; Reilly Decl. ¶27; Washington Decl. ¶26; Waggoner Decl. ¶27. Even if Petitioners somehow continue operating, they will be forced to take irreversible steps, including closing facilities and laying off employees. *See* Sheahan Decl. ¶26; Waggoner Decl. ¶31; Reilly Decl. ¶30; Washington Decl. ¶29.

A later victory would come too late. Even if DEA ultimately grants Petitioners federal registrations, the harm will be done. "It is not realistic to expect that [a business], choked of any income or business … could simply reopen its doors months, if not years, after [an agency] locked them shut." *Alpine Sec. Corp.*, 121 F.4th at 1329. Nor can Petitioners recover the goodwill of their customers and patients. *See Adya LLC v. DEA*, 826 F. Supp. 3d 115, 133-34 (D.D.C. 2026) (loss of customer goodwill constitutes irreparable harm). Patients turned away will go to competitors, if they can, and might never return. Sheahan Decl. ¶¶23-25; Reilly Decl. ¶¶28-29; Washington Decl. ¶¶27-28; Waggoner Decl. ¶¶28, 30.

B. Petitioners Will Be Unable to Recover Monetary Compensation.

Economic harm ordinarily does not constitute irreparable injury. But that rule "is based upon the presumption that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation." *Robertson v. Cartinhour*, 429 F. App'x 1, 3 (D.C. Cir. 2011) (quotation omitted). No such relief is available here. The APA waives sovereign immunity only for actions "seeking relief other than money damages." 5 U.S.C. §702. As a result, even if Petitioners manage to stay afloat until DEA processes their manufacturer applications, they will never recover the economic losses the counterparty restriction will inflict. That is irreparable harm. *See Adya LLC*, 826 F. Supp. 3d at 134.

III. The Balance of Equities and Public Interest Favor a Stay.

The balance of equities and the public interest—which merge where the government is a party, *Nken*, 556 U.S. at 435—strongly favor preserving the status quo. First, "[t]here is generally no public interest in the perpetuation of unlawful agency action." *League of Women Voters of United States v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016). Accordingly, Petitioners' "high likelihood of success on the merits is a strong indicator" that a stay is in the public interest. *Id.*

Nor is there anything close to a "balance" of equities. Absent a stay, Petitioners will be substantially and irreparably harmed. *See supra* pp. 22-25.

Meanwhile, a stay costs DEA nothing; it would simply preserve, during this litigation, the state-licensed supply chains the Order itself found sufficient to serve the public health, *see supra* pp. 3-5. Thus, a stay would restore exactly what the Order promised: continuity for patients and existing state systems. The public interest points the same way. By excluding fully compliant, state-licensed manufacturers, the counterparty restriction will create supply shortages and higher costs for Pennsylvania patients, Waggoner Decl. ¶28, and force dispensaries to close, requiring elderly, disabled, and seriously ill patients to travel farther for medication or go without, *see, e.g.*, Reilly Decl. ¶28.

CONCLUSION

Petitioners respectfully request that the Court immediately stay the counterparty restriction, set out in paragraphs 5-8 & 11 of the Guidance.

Respectfully submitted,

/s Beth C. Neitzel

Beth C. Neitzel (56001)
Counsel of Record
Campbell Curry-Ledbetter*
Kevin Y. Chen (66135)
Anjika Pai*
FOLEY HOAG LLP
155 Seaport Boulevard
Suite 1600
Boston, MA 02210
Tel. (617) 832-1000
bneitzel@foleyhoag.com
ccurryledbetter@foleyhoag.com
kchen@foleyhoag.com

Counsel for Petitioners G.P.M.II, LLC; MLH Explorations LLC; Tri-Mountain Pure, LLC; and Story PA CR, LLC,

Andrew J. Fishman*
FOLEY HOAG LLP
1301 Ave. of the Americas
25th Floor
New York, NY 10019
Tel. (212) 812-0400
afishman@foleyhoag.com

*Applications for pro hac vice admission forthcoming

Dated: November 19, 2026

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing motion complies with the word limit of Federal Rule of Appellate Procedure 27(d)(2)(A) because the motion contains 5,200 words. The motion complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 27(d)(1)(E) and 32(a)(5) and (6) because it has been prepared using Microsoft® Word for Microsoft 365 in proportionally spaced 14-point Times New Roman typeface. As permitted by Federal Rule of Appellate Procedure 32(g)(1), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ *Beth C. Neitzel*
Beth C. Neitzel

CERTIFICATE OF SERVICE

I, Beth C. Neitzel, certify that on November 19, 2026, I caused the foregoing document to be served by Federal Express, CM/ECF and by e-mail (where applicable), on:

Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Attn: Administrator Terrance C. Cole
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

United States Department of Justice
950 Pennsylvania Avenue NW
Washington, D.C. 20530

Attorney General Todd Blanche
950 Pennsylvania Avenue NW
Washington, D.C. 20530

J. Kain Day
Daniel Aguilar
U.S. Department of Justice, Civil Division, Appellate Staff
950 Pennsylvania Ave NW,
Washington, DC 20530
J.kain.day@usdoj.gov
Daniel.j.aguilar@usdoj.gov

United States Attorney's Office for D.C.
601 D Street NW
Washington, DC 20530
USADC.ServiceCivil@usdoj.gov
peter.pfaffenroth@usdoj.gov
Counsel for Respondents

/s/ *Beth C. Neitzel*
Beth C. Neitzel