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QUICK TAKE

A POST-*CHEVRON* WORLD: Implications for Rulemaking in Substance Use Disorder Policy

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OVERVIEW

In the summer of 2024, the U.S. Supreme Court decided a series of cases. Two key decisions make it easier for individuals or organizations to challenge regulations issued by federal agencies. In the past, courts generally adhered to a standard known as "*Chevron* deference," which required them to defer to a government agency's interpretations of federal law when such challenges were raised. However, one of these Supreme Court decisions takes away the requirement for deference, allowing courts to become more involved in deciding whether government agencies properly interpreted federal law when issuing existing and future regulations. The other decision extends, potentially indefinitely, the time in which a regulation can be challenged in the court. This is significant because much of addiction policy is governed by regulations, and such changes could have a substantial impact on how addiction-related laws and policies are implemented and enforced.

INTRODUCTION

In the wake of the U.S. Supreme Court's decision to overturn the 40-year doctrine of *Chevron* deference in *Loper Bright Enterprises v. Raimondo*,[1] lawmakers and administrative agencies must now navigate a post-*Chevron* landscape, where courts are no longer required to defer to an agency's interpretation of ambiguous statutes. This decision now places scrutiny of these commonplace, yet often highly specialized, agency interpretations of statutes more firmly in the hands of the court system.

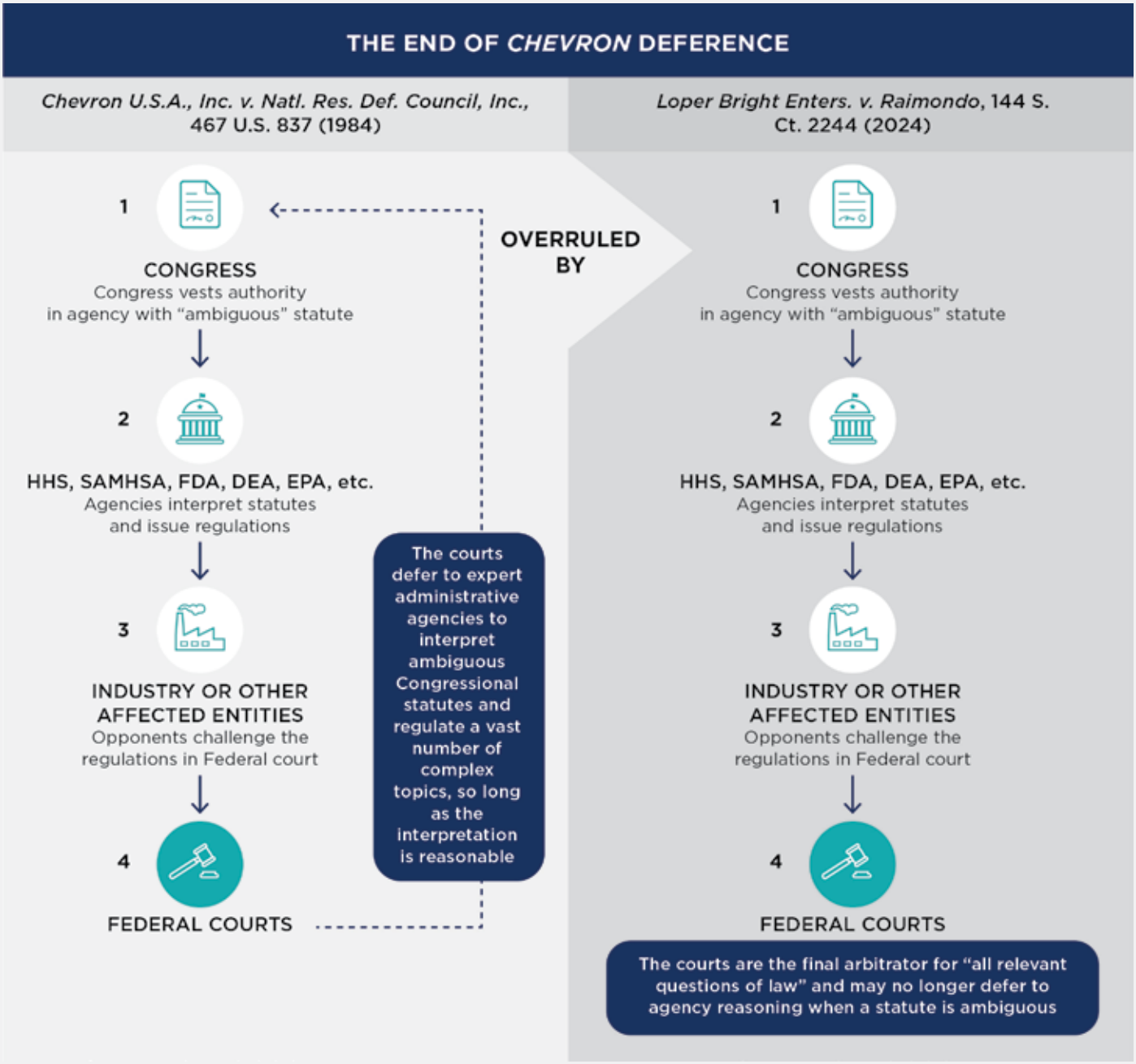
Magnifying the effect of the *Loper Bright* decision is the Supreme Court's holding in *Corner Post, Incorporated v. Board of Governors of the Federal Reserve System*,[2] which indefinitely extends the time a regulation can be challenged under the Administrative Procedure Act (APA). Together, these decisions make it easier to challenge administrative actions in court, potentially triggering "a tsunami" of regulatory challenges.[3] These decisions, however, also open the door to challenges to archaic and even harmful regulations unsupported by statutory authority.

In this brief, we explore the impact of the *Loper Bright* and *Corner Post* decisions with a focus on the regulatory and statutory framework governing substance use disorder (SUD).

Loper Bright Enterprises v. Raimondo

Administrative agencies regulate across a broad spectrum of issues that impact the lives of all Americans—from health, environment, and food safety to employment, energy, and taxes.[4] Since 1984, the doctrine of *Chevron* deference has guided courts' analysis when agency regulations are challenged, granting judicial deference to an agency's interpretation of statutory ambiguity, so long as the interpretation is reasonable.[5] The reasoning behind this landmark decision was that expert agencies, accountable to the President—and by extension the people, are better suited than the courts to make policy decisions over a vast number of increasingly complex topics.[6] In the last four decades, over 18,000 cases have been analyzed under the *Chevron* deference doctrine.[7]

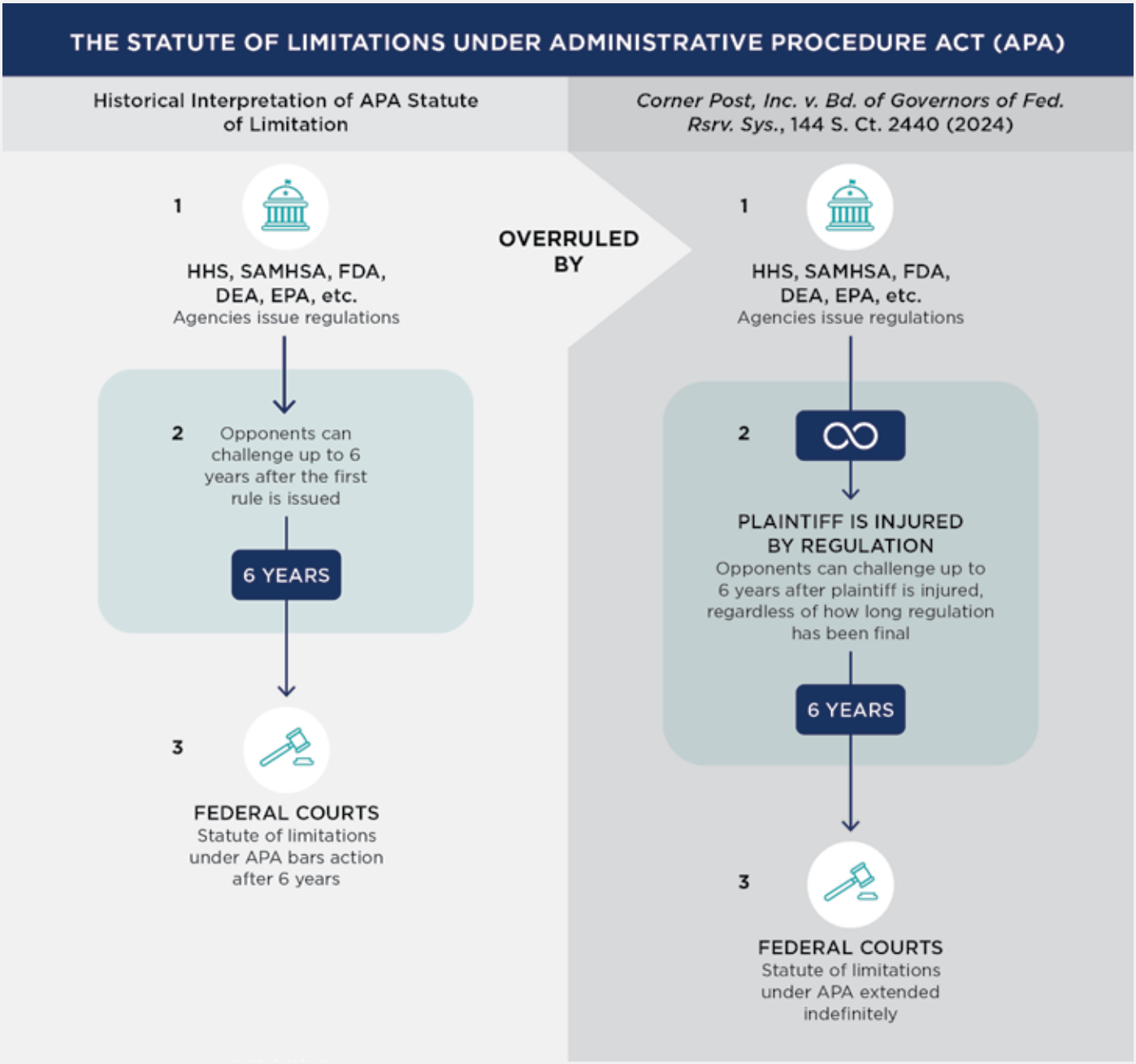
In *Loper Bright Enterprises v. Raimondo*, commercial fishermen challenged a National Marine Fisheries Service (NMFS) regulation that required Atlantic herring fisheries to pay for at-sea monitoring programs, arguing that the Magnuson–Stevens Fishery Conservation and Management Act of 1976 (Magnuson–



Stevens Act or MSA) did not grant the NMFS such authority. Relying on § 706 of the APA, which says that "the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action,"[8] the Court, in a 6-3 opinion, ruled that courts may no longer automatically defer to agency reasoning when a statute is ambiguous.[9] The Court reasoned that *Chevron* deference conflicts with the APA by allowing the Executive Branch, through administrative agencies, to infringe upon the Judiciary's power to resolve statutory ambiguities.[10] However, this holding overlooks the possibility that deferring to agency expertise could be a legitimate means for courts to resolve such ambiguities.

Corner Post, Inc., v. Board of Governors of the Federal Reserve System

Unless Congress specifies otherwise within a particular statute, the U.S. Code dictates that challenges to U.S. agency actions "be barred unless the complaint is filed within six years after the right of action first



accrues."[11] Historically, this language has been interpreted to mean that a complaint against an agency regulation could only be filed within six years of the regulation being finalized. However, in *Corner Post, Inc. v Board of Governors of the Federal Reserve System*,[12] the Court ruled that regulatory challenges can be brought within six years of the plaintiff's injury,[13] regardless of how long the regulation has been in place. This decision effectively extends the time frame to challenge a regulation indefinitely, as a new market entrant could be injured more than six years after the regulation was finalized.

SUBSTANCE USE DISORDER STATUTES AND REGULATIONS

While the post-*Chevron* landscape will take shape over time, it is fair to expect additional litigation that could challenge regulations pertaining to SUD. In terms of litigation strategy, federal agencies, lawmakers, and advocates in the SUD space must prepare to defend against challenges that may undermine services for individuals with SUD and their rights, while simultaneously identifying opportunities to challenge outdated regulations that lack statutory support. Similarly, *Corner Post* has opened the door for challenges to be brought against statutes and regulations finalized decades ago.

Methadone

Methadone is approved by the Food and Drug Administration (FDA) as both a pain reliever[14] and a medication to treat opioid use disorder (MOUD).[15] It is considered a "life-saving medication"[16] and has consistently been shown to be both safe[17] and the most effective MOUD in promoting long-term recovery[18] and reducing the risk of overdose.[19] Despite its proven safety and efficacy, methadone as a treatment for OUD is subject to one of the most stringent regulatory frameworks in the United States.[20]

The use of methadone to treat OUD is subject to dual regulatory authority from both the Drug Enforcement Administration (DEA) and the Department of Health and Human Services (HHS).[21] Under the Controlled Substances Act (CSA), Congress[22] classifies methadone as a Schedule II substance,[23] the most highly regulated class of medications that may be prescribed.[24] Notably, the scheduling[25] of methadone is more restrictive than other MOUD.[26] To prescribe, dispense, administer, or conduct research with Schedule II substances, practitioners[27] and pharmacists[28] must complete a separate registration with DEA. Compliance with these statutory requirements allow practitioners to prescribe, and pharmacists to dispense, all Schedule II drugs for any indication, except methadone specifically for the treatment of OUD.[29] As a result, methadone is the only controlled substance medication subject to two distinct regulatory frameworks, based solely on the medical condition for which it is being used.[30]

The CSA further delegates the authority to HHS to "determine the appropriate methods of professional practice in the medical treatment of narcotic addiction of various classes of narcotic addicts."[31] In 1974, the CSA was amended by the Narcotic Addict Treatment Act (NATA)[32], which granted authority to both SAMHSA[33] and the DEA[34] to oversee the establishment and operation of "narcotic treatment programs" that dispense controlled substances, such as methadone, for the treatment of OUD.[35]

> **Methadone is the only controlled substance medication subject to two distinct regulatory frameworks based solely on the medical condition for which it is being prescribed.**

Under NATA, the DEA[36] registers a practitioner "to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment," so long as SAMHSA deems the practitioner "qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought."

What that looks like in practice today is the opioid treatment program (OTP) system. Only practitioners registered to operate an OTP[37] are permitted to administer or dispense, but not prescribe, methadone for the treatment of OUD. OTPs must undergo a two-step approval process that includes both accreditation by one of only six authorized accreditation bodies[38] and certification by SAMHSA,[39] which requires having a valid DEA registration,[40] to "ensur[e] that OTPs are meeting regulatory criteria."[41] In addition, state[42] and local authorities impose additional regulations and restrictions on OTPs.[43] These regulations have resulted in a scarcity of OTPs, with 95% of Zip Code Tabulation Areas[44] in the U.S. lacking accessible methadone treatment.[45]

Federal regulations from SAMHSA also governs the operation of OTPs, including the dosing, administration, and take-home allowances for methadone as a MOUD.[46] These regulations were revised in 2024 to increase flexibility in MOUD administration. Of note, the revised regulations allow up to 28 days of take-home doses of methadone for unsupervised consumption, remove the requirement that a person be "addicted to an opioid drug" for "at least 1 year before" receiving MOUD, and include "correctional facilities registered as hospital by DEA as entities that can dispense MOUD when treating for concurrent medical conditions."[47]

Importantly, neither the Controlled Substances Act[48] nor the Narcotic Addict Treatment Act[49] specify a statute of limitations, meaning the open-ended standard described in *Corner Post* applies to potential lawsuits that could stem from many of the legal requirements noted above.

Mobile OTP units

Mobile OTP units are defined as "[OTPs] operating from a motor vehicle, as defined in this section, that serves as a mobile component (conveyance) and is operating under the registration of the [OTP], and engages in maintenance and/or detoxification treatment with narcotic drugs in schedules II-V, at a location or locations remote from, but within the same State as, its registered location."[50] Historically, mobile OTP units were required to obtain their own registration from the DEA, separate from the brick-and-mortar OTPs that operated the mobile units.[51] In 2021, the DEA, vested with authority from the Attorney General under the CSA, issued a rule waiving this separate registration requirement for mobile units, now considering the operation of a mobile unit as "a coincident activity of an existing [OTP]."[52] In 2024, SAMHSA updated its regulations concerning the operation of OTPs and mobile units to align with DEA regulations.[53]

Mobile OTP units are subject to certain restrictions under the recent DEA regulations. For example, mobile OTP units may only operate without a separate registration in the same state as their registered OTP location.[54] Additionally, OTPs must notify the DEA of their intent to operate a mobile unit[55] and submit all state and local licensing and registration documentation to DEA.[56] Although there is no mileage limit for mobile OTP units, these vehicles must return to their registered OTP location at the end of each day.[57]

Telehealth and the prescribing of MOUD

Historically, providers were required to conduct in-person evaluations of a patient before prescribing controlled substances.[58] In response to the COVID-19 pandemic, however, the DEA allowed the prescription of Schedule II-V controlled substances, including methadone (Schedule II) and

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buprenorphine (a Schedule III MOUD), via telehealth without an initial in-person evaluation. Since this initial allowance, the DEA has extended this flexibility until December 31, 2025, to ensure continuity of care.[59] In 2024, SAMHSA updated its regulations governing medications for the treatment of opioid use disorder, including rules regarding the prescribing of MOUD via telehealth.[60] Under the revised rule, providers can screen patients for buprenorphine initiation using audio-only or audio-visual telehealth technology, if the provider determines that these methods are adequate for evaluation.[61] However, providers may screen patients for the initiation of methadone using audio-visual telehealth technology only.[62] When audio-visual telehealth is unavailable, audio-only technology may be used for methadone initiation, but only if the patient is in the presence of a licensed and DEA-registered practitioner.[63]

Confidentiality of Substance Use Disorder (SUD) Patient Records

The regulations set forth in 42 C.F.R. part 2 ("Part 2") protect the records of individuals receiving care for SUD, broadly construed.[64] In 2022, SAMHSA revised these privacy regulations to align with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH).[65] Notably, these revised regulations allow a single consent for all future uses and disclosures,[66] permit the disclosure of de-identified records to public health authorities without patient consent,[67] and allow HIPAA-covered entities to re-disclose these records in accordance with HIPAA guidelines.[68] However, the use of these records in civil, criminal, administrative, and legislative proceedings against patients is prohibited without patient consent or a court order.[69] Similar to psychotherapy notes under HIPAA,[70] SUD counseling notes, which are maintained separately by a clinician, cannot be disclosed without specific patient consent. Conversely, segregation of Part 2 records from other information is not required.[71]

However, these revised regulations fail to implement HIPAA's anti-discrimination protections required under the CARES Act.[72] These protections are essential to address concerns about stigma, discrimination, and fear of prosecution, all of which deter people from seeking SUD treatment. While SAMHSA and its parent agency, HHS, have indicated that these protections will be proposed in a separate rulemaking,[73] no proposal has been made to date, leaving a gap wherein individuals with SUD remain unprotected against discrimination in various settings, including employment, housing, and healthcare.

THE FUTURE OF RULEMAKING UNDER *LOPER BRIGHT*

The federal rulemaking process is governed by the Administrative Procedure Act (APA).[74] Agencies are required to publish a proposed rule in the Federal Register and solicit public comments. The agency must then consider this public feedback, amend the proposed rule where appropriate, and then publish a final rule in the Federal Register, including its effective date and a description of and response to the public comments received.[75] Rulemaking takes time, from several months to several years, depending

on factors such as the complexity of the rule and the number of public comments received. While *Loper Bright* does not change the fundamental process for rulemaking under the APA, in addition to broader legal trends and the advancement of doctrines,[76] such as the major questions doctrine, making it easier for courts to block certain agency actions, it may reduce agencies' willingness to push novel or expansive statutory interpretations.

Increased challenges and fewer wins for agencies

Without the doctrine of *Chevron* deference, litigation challenging regulatory actions may increase. In her dissent, U.S. Supreme Court Justice Kagan argues that the authority to promulgate regulations should lie with agencies that are "staffed with 'experts in the field' who can bring their training and knowledge to bear on open statutory questions" on "subject matter that courts could not hope to."[77] Now, individual courts must exercise their "independent judgment" to assess the legitimacy of regulations that are scientific, technical, subjective, or niche—such as those defining an employee, determining the structure of a protein, distinguishing between squirrel species, or evaluating the extent that noise disrupts natural quiet.[78] Courts, armed with this new standard, may subject agency regulations to greater scrutiny in legal challenges. A potential consequence is less success for agencies defending their regulations. Even under *Chevron deference*, federal agencies prevailed in only about 70 percent of legal challenges to their rules.[79] The uncertainty caused by pending litigation and suspended regulations could bring some agency actions to a halt, leaving Americans in limbo.

Slower rulemaking process

The death of *Chevron* deference could also also impede the speed at which federal agencies promulgate rules, as they will need to exercise greater caution in crafting rules to withstand judicial review. When Congress explicitly authorizes an agency to exercise discretion in rulemaking, the agency must demonstrate persuasively that it is acting within the scope of that delegated authority.[80] However, when Congress empowers an agency to promulgate rules to "fill in the gaps" of a statutory framework or engage in regulatory oversight "with flexibility," the agency must ensure that its interpretation of this authority clearly aligns with Congressional intent.[81]

Difficulty "filling in gaps"

In the absence of *Chevron* deference, uncertainty surrounds future rulemaking. Embedded within *Chevron* deference is the principle that Congress delegated authority to agencies because it "value[d] the agency's experience with how a complex regulatory regime functions, and with what is needed to make it effective."[82] Congress often intentionally incorporates ambiguity in statutory language, allowing the agency's subject matter expertise to maneuver and respond to the evolving landscape of their technical purview.[83] Without deference to this expertise, agencies will struggle to issue rules in a changing, complex world—one that even Congress could not fully foresee. Instead, it will be the federal judiciary—with over 1,700 judges of diverse philosophical and ideological backgrounds across 209 federal courts[84]—that will play an even greater role in shaping the administrative state going forward.

In *Chevron's* absence, the Court invokes *Skidmore* deference, which instructs that the "weight" attributed to an agency's interpretation "depend[s] upon the thoroughness evident in [the agency's] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control."[85] This approach also aligns with *de novo* (or fresh) review—specifically, what the Court refers to as "independent judgment."[86]

Potential impact on SUD regulations

While these effects will become clearer as agencies and courts digest *Loper Bright* and *Corner Post*, the question for the courts will continue to be whether the regulation goes beyond what the law passed by Congress allows. SAMHSA's authority to regulate methadone for the treatment of OUD is derived from 21 U.S.C. § 823(h), stating that the DEA shall issue registration to dispense Schedule II controlled substances for treatment:

> **(1) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;**
>
> **. . . .**
>
> **(3) if the Secretary determines that the applicant will comply with standards established by the Secretary. . . respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.**[87]

In subsection (1), SAMHSA is granted broad authority to establish the standards they must uphold with regard to OTP practitioner accreditation and certification.[88] This broad authority grants SAMHSA the power to amend the current, burdensome administrative framework that currently governs the OTP system.[89]

Subsection (3) specifically delegates to SAMHSA the authority to set standards for the unsupervised use of MOUD.[90] Therefore, SAMHSA's recent flexibility in take-home allowances[91] likely fits squarely within this statutory authority. However, other revisions may be considered outside the scope of SAMHSA's statutory authority.

However, advocates and non-government organizations (NGOs) should view this new regulatory landscape as an opportunity to raise regulatory challenges long thought to be futile or expired. For instance, the rules governing mobile OTP units may provide a unique opportunity to examine whether they exceed statutory authority.

IMPLICATIONS FOR STATES

While *Loper Bright* does not directly apply to state agency decisions, recent trends show state courts rejecting deference in favor of independent review of state agency actions. Florida, Louisiana, Mississippi, and Tennessee already use *de novo* review for challenges to state agency decisions, while North Carolina, Pennsylvania, and Texas, utilize a "hybrid" approach.[92] In the meantime, states can capitalize on the uncertainty in the federal realm. Some of the most progressive public health measures, such as banning the sale of flavored tobacco products, have occurred at the state level.[93]

Advocates for addiction policy reform should view this post-*Chevron* world as an opportunity to reexamine existing regulations, while also weighing the potential risks of challenging these regulations.

RECOMMENDATIONS

Congress

While *Loper Bright* addresses the courts' authority to independently review agency action, the impetus is now on Congress to legislate with greater specificity or delegate interpretative authority to agencies. Clear, definitive grants of statutory authority will be essential to safeguard future agency action. Similarly, Congress can amend "ambiguous" statutes to clarify agency authority.

Congress can also take the lead in enshrining evidence-based SUD policies into federal law. The Modernizing Opioid Treatment Access Act, introduced in Congress in 2023, would waive CSA provisions requiring qualified practitioners to obtain a separate DEA registration to prescribe and dispense methadone to treat OUD. Additionally, the bill would allow methadone for OUD to be dispensed through pharmacies for unsupervised use.[94] This legislation is intended to increase access to methadone at a time when opioids are responsible for over 70% of all overdose deaths.[95]

Executive Branch

For agencies, *Loper Bright* and *Corner Post* mark a new era in rulemaking. In his concurrence, U.S. Supreme Court Justice Gorsuch urges agencies to provide thorough analyses of their statutory alignment, emphasizing the legislative text, its context, canons of construction, and other evidence of Congressional intent.[96] To that end, agencies will need to continue to be deliberate in their rulemaking, ensuring regulations are clearly and directly tied to statutory language.

There may be opportunities in addiction policy to challenge an agency's interpretation as exceeding Congressional intent. One example of potential overreach is the DEA's regulatory definition of "individual practitioner," which specifically excludes pharmacists and pharmacies from dispensing methadone for OUD treatment.[97] This definition, however, is significantly narrower than Congress's definition of "practitioner"[98] under the CSA, which permits pharmacies and pharmacists "to distribute, dispense, [or] administer a controlled substance in the course of professional practice or research."[99] A broader definition of "practitioner" would also align with SAMHSA's definition of "practitioner" in its 2024 revised regulations.[100] While this challenge alone would be insufficient to meaningfully increase access to methadone for the treatment of OUD, it could be part of a larger litigation strategy to challenge the current, restricted OTP system.

NGOs

Loper Bright and *Corner Post* may provide an opportunity to challenge existing regulations. Under *Corner Post*, long-standing regulations may now be subject to legal scrutiny. For instance, advocates could consider a litigation strategy that leverages *Corner Post* to attack the DEA definition of "practitioner" from the 1970s. While it is important for advocates to prepare to defend against challenges to recent flexibility in regulations, they should also take a closer look at whether agencies have issued rules that exceed their statutory authority.

CONCLUSION

While these recent cases overturn long-standing precedent and could disrupt the regulatory landscape in the United States, they also present opportunities to reassess established rules. Moving forward, it is crucial for advocates to work with Congress to include clear, explicit grants of authority in future legislation, allowing agencies to continue providing vital services to Americans.

ENDNOTES

1 Loper Bright Enters. v. Raimondo, 144 S. Ct. 2244 (2024).

2 Corner Post, Inc., v. Bd. of Governors of the Fed. Rsrv. Sys., 144 S. Ct. 2440 (2024).

3 *Id.* at 2482 (Jackson, J. dissenting).

4 *The Executive Branch*, The White House, https://www.whitehouse.gov/about-the-white-house/our-government/the-executive-branch/ (last visited Nov. 26, 2024) (describing different agencies and their areas of expertise).

5 Chevron U.S.A. v. Natl. Res. Def. Council, 467 U.S. 837, 844–45 (1984).

6 *Id.* at 865–66. See also Thomas W. Merrill, *The Story of* Chevron: *The Making of an Accidental Landmark*, 66 Admin. L. Rev. 253, 256–57 (2014).

7 Loper Bright Enters. v. Raimondo, 144 S. Ct. 2244, 2307 (2024) (Kagan, J. dissenting).

8 Administrative Procedure Act, 5 U.S.C. § 706 (defining the scope of review for courts).

9 *Loper Bright*, 144 S. Ct. at 2273 (holding that "courts need not and under the APA may not defer to an agency interpretation of the law simply because a statute is ambiguous").

10 *Id.* at 2274 (Thomas, J. concurring).

11 28 U.S.C. § 2401(a).

12 144 S. Ct. 2440, 2448–49 (2024) (holding that a convenience store that opened in 2018 could bring an action in 2021 against the Federal Reserve over a regulation finalized in 2014).

13 *Id.* at 2450 (stating that a "complete and present cause of action" is when a plaintiff's right to "file suit and obtain relief" arises).

14 Inst. of Med. (U.S.) Comm. on Fed. Regul. of Methadone Treatment, Federal Regulation of Methadone Treatment (Richard A. Rettig & Adam Yarmolinsky eds., National Academies Press 1995), https://www.ncbi.nlm.nih.gov/books/NBK232114/ [hereinafter Federal Regulation of Methadone Treatment].

15 *Fifty years after landmark methadone discovery, stigmas and misunderstandings persist*, Rockefeller Univ. (Dec. 9, 2016), https://www.rockefeller.edu/news/12410-fifty-years-after-landmark-methadone-discovery-stigmas-and-misunderstandings-persist/; *Information about Medications for Opioid Use Disorder (MOUD),* Food & Drug Admin. (May 22, 2024), https://www.fda.gov/drugs/information-drug-class/information-about-medications-opioid-use-disorder-moud.

16 *WHO Model Lists of Essential Medicines*, World Health Org. (Sept. 2021), https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists.

17 *Methadone*, Substance Abuse & Mental Health Servs. Admin. (Mar. 29, 2024), https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/methadone.

18 Pengyue Zhang et al., Ex*amining differences in retention on medication for opioid use disorder: An analysis of Ohio Medicaid data*, J. Substance Abuse Treatment (Mar. 17, 2022), https://www.sciencedirect.com/science/article/abs/pii/S0740547221004128?via%3Dihub.

19 Sarah E. Wakeman et al., *Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder*, JAMA Network Open (Feb. 5, 2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2760032.

20 Bridget C.E. Dooling & Laura E. Stanley, *Methadone's Regulatory Thicket*, 32 Annals Health L. & Life Scis. 191, 191 (2023).

21 See Johnathan H. Duff, Cong. Rsch. Serv., IF12348, Medications for Opioid Use Disorder 1–2 (2023); see *Methadone Treatment: Recent Revision to Regulation Covering Facilities Treating Individuals for a Primary Diagnosis Other Than Opioid Use Disorder*, Legis. Analysis & Pub. Pol'y Ass'n 1–2 (June 2024), https://legislativeanalysis.org/wp-content/uploads/2024/07/Methadone-Factsheet-FINAL.pdf.

22 Dooling & Stanley, *supra* note 20, at 212. The Attorney General delegated the authority to revisit classifications of controlled substances to the DEA. 28 C.F.R. § 0/100(b) (2023).

23 Comprehensive Drug Abuse Prevention and Control Act (or Controlled Substances Act) of 1970, 21 U.S.C. § 812(Schedule II)(b)(1).

24 Dooling & Stanley, *supra* note 20, at 212; For example, a prescription for a Schedule II substance must be in written form and may not be refilled. 21 C.F.R. §§ 1306.11–12 (2023). Conversely, a prescription for a Schedule III substance can be conveyed verbally and may be refilled up to five times. 21 C.F.R. §§ 1306.21–22 (2023).

25 21 U.S.C. § 812(b).

26 Two other MOUD, buprenorphine (Schedule III) and naltrexone (unscheduled by DEA), are also approved by the FDA. *Buprenorphine*, Substance Abuse & Mental Health Servs. Admin. (Mar. 28, 2024), https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/buprenorphine; *Naltrexone*, Substance Abuse & Mental Health Servs. Admin. (Mar. 29, 2024), https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/naltrexone.

27 Phillip Zhang & Preeti Patel, *Practitioners and Prescriptive Authority*, StatPearls (Sept. 19, 2022, 11:59 AM), https://www.statpearls.com/point-of-care/131545.

28 U.S. Drug Enf't Admin., U.S. Dep't of Just., EO-DES154R1, Pharmacist's Manual: An Informational Outline of the Controlled Substances Act 15 (2022) ("Every pharmacy that dispenses controlled substances must be registered with DEA."); *see also* 21 U.S.C. 823(f); 21 C.F.R. 1301.11(a).

29 *See generally* Dooling & Stanley, *supra* note 20.

30 *See* Federal Regulation of Methadone Treatment, *supra* note 14.

31 HHS determines appropriate practice "after consultation with the Attorney General and with national organizations representative of persons with knowledge and experience in the treatment of narcotic addicts." 42 U.S.C. § 290bb-2a.

32 Narcotic Addict Treatment Act of 1974 (NATA), Pub. L. No. 93-281, 88 Stat. 124.

33 In 2001, HHS delegated its authority to the Substance Abuse and Mental Health Services Administration (SAMHSA) to provide oversight for "narcotic treatment programs." 42 C.F.R. § 8.1(a) (2024) (delegating authority to SAMHSA to certify OTPs).

34 21 C.F.R. ch. II (authorizing the DEA to oversee registration for dispensing controlled substances for treating OUD under the CSA).

35 *See* Duff, *supra* note 21. See also 21 U.S.C. § 823(h) (requiring annual registration for practitioners to dispense controlled substances for maintenance treatment); 42 C.F.R. § 8.1(a) (2024) (delegating authority to SAMHSA to certify OTPs); 42 C.F.R. § 8.11(c)(3) (2024) (providing that DEA will be notified once SAMHSA determines an OTP meets certification requirements).

36 21 C.F.R. ch. II (authorizing the DEA to oversee registration for dispensing controlled substances for treating OUD under the CSA).

37 21 C.F.R. § 1306.07(a) (2024). The terms opioid treatment program (OTP) and narcotic treatment program (NTP) are interchangeable. However, this QuickTake will use OTP exclusively. *Opioid (Narcotic) Treatment Program Services (OTP/NTP Sample Clauses)*, Law Insider, https://www.lawinsider.com/clause/opioid-narcotic-treatment-program-services-otp-ntp (last visited Nov. 25, 2024).

38 *Certification of Opioid Treatment Programs (OTPs)*, Substance Abuse & Mental Health Servs. Admin. (June 11, 2024), https://www.samhsa.gov/medications-substance-use-disorders/become-accredited-opioid-treatment-program; *Approved Accreditation Bodies*, Substance Abuse

& Mental Health Servs. Admin. (Aug. 29, 2024), https://www.samhsa.gov/medications-substance-use-disorders/become-accredited-opioid-treatment-program/approved-accreditation-bodies.

39 *See generally Federal Guidelines for Opioid Treatment Programs*, Substance Abuse & Mental Health Servs. Admin. (Jan. 2015), https://store.samhsa.gov/sites/default/files/d7/priv/pep15-fedguideotp.pdf.

40 See Duff, *supra* note 21, at 2.

41 *Certification of Opioid Treatment Programs (OTPs)*, *supra* note 38.

42 In 2022, nearly 100% of states imposed additional regulations on the establishment and/or operation of OTPs. *Overview of Opioid Treatment Program Regulations by State*, Pew Charitable Trs. (Sept.19, 2022), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2022/09/overview-of-opioid-treatment-program-regulations-by-state.

43 *Id.*

44 Zip Code Tabulation Areas (ZCTAs) are generalized representations of U.S. Zip Code areas used by the U.S. Census Bureau to map and analyze statistical data from censuses and surveys based on zip codes. *Zip Code Tabulation Areas (ZCTAs)*, U.S. Census Bureau (Aug. 10, 2023), https://www.census.gov/programs-surveys/geography/guidance/geo-areas/zctas.html.

45 Sadia Jehan et al., *Geographic variation in availability of opioid treatment programs across U.S. communities*, 42 J. Addictive Diseases 136, 136 (2024), https://www.tandfonline.com/doi/full/10.1080/10550887.2023.2165869.

46 *See generally* 42 C.F.R. pt. 8 (2024).

47 Medications for the Treatment of Opioid Use Disorder, 89 Fed. Reg. 7528, 7549 (Feb. 2, 2024) (to be codified at 42 C.F.R. pt. 8).

48 Comprehensive Drug Abuse Prevention and Control Act (or Controlled Substances Act) of 1970, 21 U.S.C. §§ 871–890.

49 Narcotic Addict Treatment Act of 1974 (NATA), Pub. L. No. 93-281, 88 Stat. 124.

50 21 C.F.R. § 1300 (2024).

51 Jason Brian Gibbons, *New Federal Rules Make It Much Easier to Expand Access to Treatment*, Johns Hopkins Bloomberg Sch. of Pub. Health (July 28, 2022), https://opioidprinciples.jhsph.edu/new-federal-rules-make-it-much-easier-to-expand-access-to-treatment/.

52 Registration Requirements for Narcotic Treatment Programs with Mobile Components, 86 Fed. Reg. 33861, 33861–62 (June 28, 2021).

53 42 C.F.R.§ 8.11(h)(1) (2024).

54 Registration Requirements for Narcotic Treatment Programs with Mobile Components, 86 Fed. Reg. at 33862.

55 *Id.* at 33864.

56 U.S. Bureau of Just. Assistance, U.S. Dep't of Just., NCJ-302609, DEA Expands Access to Mobile Narcotic Treatment Programs 2 (2021), https://www.cossup.org/Content/Documents/Articles/RTI_DEA_Rule_Article.pdf.

57 *Id.*

58 Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. No. 110–425, 122 Stat 4820.

59 Third Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 89 Fed. Reg. 91253, 91253 (Nov. 19, 2024).

60 Medications for the Treatment of Opioid Use Disorder, 89 Fed. Reg. 7528, 7529 (Feb. 2, 2024).

61 *Id.* at 7533; 42 C.F.R. § 8.12(f)(2)(v) (2024).

62 Medications for the Treatment of Opioid Use Disorder, 89 Fed. Reg. at 7558 ("In evaluating patients for treatment with schedule II medications (such as Methadone), audio-visual telehealth platforms must be used.").

63 42 C.F.R. § 8.12(f)(2)(v)(A) (2024).

64 42 C.F.R. § 2.1 (2024); 42 U.S.C. § 290dd-2(a).

65 *Fact Sheet 42 CFR Part 2 Final Rule*, U.S. Dep't of Health & Hum. Servs. (Feb. 8, 2024), https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html.

66 42 C.F.R. § 2.12(d)(2)(i)(C) (2024).

67 42 C.F.R. § 2.54(b) (2024), but also must align with HIPAA Privacy Rule 45 C.F.R. § 164.514(b) (2024).

68 *Fact Sheet 42 CFR Part 2 Final Rule*, *supra* note 65.

69 42 C.F.R. § 2.63(a)(3) (2024).

70 *Does HIPAA Provide Extra Protections for Mental Health Information Compared with Other Health Information?*, U.S. Dep't of Health & Hum. Servs. (Sept. 12, 2017), https://www.hhs.gov/hipaa/for-professionals/faq/2088/does-hipaa-provide-extra-protections-mental-health-information-compared-other-health.html.

71 *Fact Sheet 42 CFR Part 2 Final Rule*, *supra* note 65.

72 Confidentiality of Substance Use Disorder (SUD) Patient Records, 89 Fed. Reg. 12472, 12481 (Feb. 16, 2024) (stating that "the Department intends to implement the CARES Act anti[-]discrimination provisions in a separate rulemaking").

73 *Id.*

74 Administrative Procedure Act, 5 U.S.C. §§ 551–559 (1946); *Learn About the Regulatory Process*, Regulations.gov, https://www.regulations.gov/learn (last visited Nov. 25, 2024).

75 Todd Garvey, Cong. Rsch. Serv., RF41546, A Brief Overview of Rulemaking and Judicial Review 3 (2017).

76 Andrew Twinamatsiko & Katie Keith, *Slouching Towards Deregulation: The Threat to Health Policy*, O'Neill Inst. for Nat'l & Global Health L. (Apr. 2022), https://oneill.law.georgetown.edu/wp-content/uploads/2022/04/ONL_Derugulation_Report_P4.pdf.

77 Loper Bright Enters. v. Raimondo, 144 S. Ct. 2244, 2298 (2024) (Kagan, J. dissenting).

78 *Id.* at 2296–97.

79 Kent Barnett & Christopher J. Walker, Chevron *in the Circuit Courts*, 116 Mich. L. Rev. 1, 6 (2017).

80 *Loper Bright*, 144 S. Ct. at 2263 (stating that courts are to ensure that agencies are acting within their delegated authority).

81 *Id.*

82 *Id.* at 2298 (Kagan, J. dissenting).

83 *Id.* at 2301 (Kagan, J. dissenting) (asserting that, of ambiguities in statutory language, "many are not" unintentional and regardless, Congress's intent is the "delegation of regulatory power to the agency and the agency's special competencies").

84 *United States Federal Courts*, Ballotpedia, https://ballotpedia.org/United_States_federal_courts (last visited Nov. 25, 2024).

85 Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944) (holding that agency interpretations "constitute a body of experience and informed judgment" that may be "entitled to respect").

86 *Loper Bright*, 144 S. Ct. at 2258–62.

87 21 U.S.C. §§ 823(h)(1), (3).

88 21 U.S.C. § 823(h)(1); 42 C.F.R. § 8.1 (2024).

89 *See* Dooling & Stanley, *supra* note 20, at 229–30; see also 42 C.F.R. §§ 8.3–8.6, 8.11 (2024).

90 21 U.S.C. § 823(h)(3); 42 C.F.R. § 8.1 (2024).

91 Medications for the Treatment of Opioid Use Disorder, 89 Fed. Reg. 7528, 7529 (Feb. 2, 2024).

92 J. Dillion Pitts & Amanda Jones Tollison, *Supreme Court's Loper Bright Decision Likely to Bolster State Trend of Abandoning Chevron Deference*, JD Supra (July 3, 2024), https://www.jdsupra.com/legalnews/supreme-court-s-loper-bright-decision-8939576/.

93 *SLATI Overview*, Am. Lung Assoc., https://www.lung.org/policy-advocacy/tobacco/slati/slati-overview (last visited Nov. 21, 2024).

94 Modernizing Opioid Treatment Access Act, S.R. 644, 118th Cong. (2023).

95 *U.S. Overdose Deaths Decrease in 2023, First Time Since 2018*, Nat'l Ctr. for Health Stats. (May 15, 2024), https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2024/20240515.htm.

96 Loper Bright Enters. v. Raimondo, 144 S. Ct. 2244, 2285–86 (2024) (Gorsuch, J. concurring).

97 21 C.F.R. § 1300.01(a) (2024) (defining an "individual practitioner" as "a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.").

98 21 U.S.C. 802(21) (defining "practitioner" as "a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.").

99 *Compare id.* with 21 C.F.R. § 1300.01(a) (2024). *See* 21 C.F.R. §1306.02 ("Any term contained in this part shall have the definition set forth in section 102 of [the CSA] (21 U.S.C. 802) or part 1300 of this chapter.").

100 Medications for the Treatment of Opioid Use Disorder, 89 Fed. Reg. 7528, 7537 (Feb. 2, 2024) (expanding the definition of "practitioner" to include multiple types of health care professionals who are "appropriately licensed by a State to prescribe and/or dispense medications for opioid use disorder within an OTP").

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