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Healthcare Alert

July 2, 2024

Chevron overruled: Insights and impacts on the healthcare industry

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The Supreme Court dramatically shifts power away from administrative agencies to federal courts. We discuss what this might mean for the healthcare industry in the coming decades.

What's the impact?

- Four recent opinions upend nearly forty years of precedent and are predicted to reshape the landscape of federal administrative law now that courts are no longer required to defer to agencies' interpretations of the statutes they administer.
- The change in framework provides new opportunities to challenge rules or regulations that were previously thought to be beyond reproach under *Chevron*.

The Supreme Court shifted significant power to the courts to interpret laws that govern US agencies in a foursome of decisions handed down in the final days of the Court's 2024 term including, *Loper Bright Enterprises, et al. v. Gina Raimondo, Secretary of Commerce, et al.; Relentless, Inc., et al. v. Department of Commerce, et al.;* and *Corner Post Inc. v. Board of*

Governors of the Federal Reserve System. These decisions will reshape the landscape of federal administrative law and upend nearly forty years of precedent. Most notably, courts are no longer required to defer to agencies' interpretations of the statutes they administer.

What is "Chevron deference?"

For over forty years, *Chevron v. Natural Resources Defense Council* provided a framework within which courts evaluated administrative agencies' interpretations of "ambiguous" statutes authored by Congress.[1] *Chevron* directed courts to first assess whether Congress had "directly spoken to" the question at issue in the case, and then, if it had not, or if the statute was ambiguous or silent on that issue, defer to an agency's interpretation of the statute if it amounted to a "permissible construction" of the statute.[2]

Now, the Supreme Court has overruled this "two-step" framework, shifting authority to determine congressional intent from regulators to federal courts.

Loper and its companion cases will have significant impacts on all areas of American life shaped by federal regulations including climate change, the financial system, transportation, healthcare, and the development of AI. As the dissent put it, "[i]n every sphere of current or future federal regulation, expect courts from now on to play a commanding role." J. Kagan, dissenting, p. 32.

In this alert, we consider just one of the open questions posed by Justice Kagan as a result of the holding in *Loper*: "What will the Nation's health-care system look like in the coming decades?"

Challenges to *Chevron*

The petitioners in both *Loper Bright* and *Relentless, Inc*. were Atlantic herring fishery businesses which challenged a rule under the Magnuson-Stevens Fishery Conservation and Management Act (MSA), administered by the National Marine Fisheries Service (NMFS). In both cases, the petitioners claimed that the rule did not authorize the NMFS to force them to pay for third-party observers to board their vessels for the purpose of data collection, as other vessels and specific categories of fishing enterprises were required to do, pursuant to a fishery management plan.

In *Loper Bright,* the DC District Court granted summary judgment for the Government, reasoning that the MSA authorized the rule, and that the rule was not ambiguous, but even if it were, deference to the NMFS's interpretation of the rule would be warranted under *Chevron*.[3] The DC Circuit affirmed, applying *Chevron* and concluding that the agency's interpretation was a

[1] 467 US 837 (1984).

[2] 467 US at 842-43.

[3] 544 F. Supp. 3d 82, 107 (DC 2021).

"reasonable" construction of the MSA.[4] The courts in *Relentless, Inc.* reached the same result. First, the Rhode Island District Court granted summary judgment for the Government, deferring to the NMFS's interpretation of the rule under *Chevron*.[5] The First Circuit affirmed, concluding that the agency's interpretation of the rule did not "exceed the bounds of the permissible" under *Chevron*'s two-step framework.[6]

The Supreme Court's decision in *Loper*

The Supreme Court granted certiorari in both cases to address only whether *Chevron* should be overruled or clarified. In a 6–3 decision, in a majority decision penned by Chief Justice Roberts, the Court expressly overruled *Chevron*, concluding that it is inconsistent with the Administrative Procedure Act (APA). In doing so, the Supreme Court directs district court judges to now "exercise their independent judgment in deciding whether an agency has acted within its statutory authority," without any specific level of deference to an agency's interpretation of a challenged statute.[7] Going forward, courts "need not and [...] may not defer to an agency interpretation of the law simply because a statute is ambiguous."

After discussing the history of the judicial role in making determinations of statutory interpretation, the Court turned to the text of the APA, which provides that "[t]o the extent necessary to decision and when presented, 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." 5 U. S. C. §706. It further directs courts to "hold unlawful and set aside agency action, findings, and conclusions found to be ... not in accordance with law." § 706(2)(A).

About forty years after the APA was enacted, *Chevron* announced the now-defunct two-step framework for review of a challenged administrative action. According to the majority in *Loper Bright*, *Chevron*'s premise that statutory ambiguity should be left to the agency to resolve was misplaced. The Court reasoned that *Chevron*'s dictate that courts afford "binding deference to agency interpretations" was inconsistent with the APA's command that "the reviewing court" should "decide all relevant questions of law" and "interpret ... statutory provisions." The majority of the justices rejected any suggestion that agencies, rather than courts, are better suited to determine what ambiguities in a federal law might mean.

Going forward, "Courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the APA requires." Ambiguity in congressional intent, or "gaps" in a given statute, will no longer be resolved in favor of an executive agency's

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[4] *See* 45 F. 4th 359 (2022).

[5] *See* 561 F. Supp. 3d 226, 234-38 (R.I. 2021).

[6] *See* 62 F. 4th 621 (2023).

[7] *Loper Bright Enterprises, et al. v. Gina Raimondo, Secretary of Commerce, et al.*, 603 U.S. ___ (2024).

interpretation. Instead, judges will exercise their "independent judgment" to resolve such questions. But the Court did not completely discount agency interpretations, stating "[c]areful attention to the judgment of the Executive Branch may help inform that inquiry." The Court reaffirmed a doctrine known *as* Skidmore deference that courts may "seek aid from the interpretations of those responsible for implementing the particular statutes," consistent with the APA. *See Skidmore v. Swift & Co.*, 323 U. S. 134, 140. In addition, court deference to agency fact-finding remains undisturbed by the decision.

The impact of the Supreme Court's decision on the healthcare industry

The healthcare industry in the United States is one of the most highly regulated industries, with myriad ever-changing rules, regulations, and interpretive guidance. Going forward, regulations across a variety of industries will be more easily challenged in court under the APA, and less insulated from judicial review.

This shift will be acutely felt in the healthcare industry, which is governed by a complex web of federal, state, and local agencies, including the Department of Health and Human Services (HHS), including HHS agencies such as the Centers for Medicare and Medicaid Services (CMS), Office of Inspector General (OIG), and the Food and Drug Administration (FDA). While there will be no "overnight" impact, we expect a material increase in legal challenges to both existing and new regulations or other decision-making by federal agencies. These challenges are expected to have a cascade of long-term effects, including less certainty regarding compliance, more opportunity to challenge federal agency policies, and slower, more methodical, agency rulemaking.

As more regulations and agency decisions are called into question, their interpretations will be left in the hands of judges instead of the agencies administering them, which could lead to inconsistent results and uncertainty across the legal landscape. The majority seemed to recognize that its decision will result in less uniform construction of federal law, stating "there is little value in imposing a uniform interpretation of a statute if that interpretation is wrong." This means that the interpretation of federal regulations governing healthcare could vary by federal Circuit, or even by state, unless competing interpretations are resolved by the Supreme Court. Moreover, although the majority stated that its decision "does not call into question prior cases that relied on the *Chevron* framework," the dissent was quick to point out that "some agency interpretations never challenged under *Chevron* now will be." For those healthcare companies deliberately operating in compliance with applicable sub-regulatory guidance, might they risk scrutiny or enforcement if a court decides such guidance was wrong? The future presents obvious compliance challenges for healthcare companies and administrators, particularly those operating across multiple jurisdictions.

At the same time, the change in framework provides new opportunities to challenge rules or regulations that were previously thought to be beyond reproach under *Chevron*. Industry stakeholders now have more opportunities to hold federal agencies accountable for sub-regulatory guidance or arbitrary decisions. To take just one example, the ways in which pandemic relief funding was distributed to healthcare providers due to the COVID-19 pandemic under the CARES Act and companion legislation are now more susceptible to legal challenge. That legislation directed trillions of dollars to HHS with very few parameters regarding who was eligible and how it should be distributed. HHS filled that ambiguity with its own judgment regarding how funds should be used and distributed , but courts no longer need to defer to the agency when determining whether its distribution of funding was appropriate under the APA.

Even regulations passed years or decades ago are subject to legal challenge. Indeed, the Court expanded the statute of limitations to challenge a rule or regulation under the APA on Monday July 1 in *Corner Post Inc. v. Board of Governors of the Federal Reserve System*. Now, legal challenges to federal regulations can be brought outside the statute of limitations if someone is not adversely affected until after the six-year window of time to file suit. For example, *Corner Post* was brought by a North Dakota truck stop, which opened for business in 2018 and in 2021 began challenging a 2011 cap on debit-card transaction fees, saying it unduly favors big banks. The implications for healthcare are vast and will allow new market entrants the opportunity to challenge rules or regulations that were previously thought to be settled.

In the context of healthcare, examples of other legal challenges include CMS's condition of participation/payment (CoPs) or condition for coverage (CfCs) rules, and fiscal year reimbursement rates. Complex challenges are also likely to arise with respect to the demarcation between FDA's legal interpretation of laws and matters where FDA's scientific expertise should receive deference, as well as the role that FDA guidance documents should play in agency enforcement decision-making.

At the agency level, we expect this power-shift to result in slower and less dramatic agency rulemaking. Agencies like HHS will have diminished ability to create new programs or impose new requirements that are not clearly authorized by the underlying legislation. This agency restriction will now go beyond the "major questions" doctrine announced by the Supreme Court in *West Virginia v. EPA*, 142 S. Ct. 2587 (2022). This may result in slower and more deliberate rule making as cautious agencies seek to craft regulations that will withstand enhanced judicial scrutiny.

The future of healthcare regulation

The Supreme Court's power shift in agency law will change the ways in which government regulates healthcare for years to come, creating both uncertainty and opportunity for market participants.

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