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## Supreme Court Opens Window To Challenge Federal Healthcare Rules

*"Chevron is overruled. Courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the APA requires." – Loper Bright, 2024*

In a landmark decision, the U.S. Supreme Court has overturned the "*Chevron* doctrine," fundamentally altering the landscape of administrative law and federal regulatory oversight in the United States. In the recent case, two industrial fishing businesses challenged the U.S. Department of Commerce's interpretation of a fishery and conservation statute. The Court's ruling has called into question decades of administrative and constitutional law. Since the healthcare industry is so heavily regulated by various state and federal agencies, existing federal rules and regulations may soon be called into question.

### Background of '*Chevron*'

The *Chevron* doctrine, a legal precedent established by the Supreme Court in the 1984 case *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, generally required courts to defer to administrative agencies' interpretations of the statutes they administer. This principle has limited judicial review of agency action for nearly four decades, granting agencies considerable latitude in interpreting statutes within their regulatory purview. Out of *Chevron* came the "*Chevron* Test," used to determine when a court should defer to an agency's interpretation of the law. In essence, the test asks whether Congress has directly addressed the precise issue in question and if not, whether the agency's interpretation is reasonable. If Congress was silent and the agency's interpretation was reasonable, the court would defer to the agency's interpretation. Now, however, the Court's ruling in *Loper Bright Enterprises v. Raimondo* and *Relentless, Inc. v. Department of Commerce* may have significant implications for healthcare organizations, influencing how healthcare laws are interpreted and enforced.

### The overturning decision: '*Loper Bright*'

*Loper Bright Enterprises* and *Relentless Inc.*, both fishing businesses, filed a lawsuit challenging a rule issued by the Department of Commerce under the Magnuson-Stevens Fishery Conservation and Management Act (MSA). The rule mandated that the businesses pay for government-approved fishing monitors required by the MSA. The plaintiffs contended that the rule was not authorized by the governing statute, which did not explicitly specify who should bear the cost of these monitors. The district court granted summary judgment in favor of the government, finding that *Chevron* deference was warranted for the agency's interpretation. The U.S. Court of Appeals for the District of Columbia Circuit affirmed the decision in a divided panel. The Supreme Court accepted the case to address the limited question of whether *Chevron* should be overruled. The Court held that the Administrative Procedure Act requires courts to utilize independent judgment in determining whether an agency has acted within its statutory authority and that courts may not defer to an agency interpretation merely because a statute is ambiguous. Since both lower courts relied on *Chevron*, the Supreme Court vacated and remanded the petitioners' cases for proceedings consistent with its ruling.

The Court's decision to overturn *Chevron* marks a profound shift in administrative law. No longer will courts automatically defer to agency interpretations of ambiguous statutes. Instead, judicial review will become more stringent, with courts assuming a more active role in interpreting the statutes in question.

"The better presumption is therefore that Congress expects courts to do their ordinary job of interpreting statutes, with due respect for the views of the Executive Branch." – Loper Bright, 2024

In the majority opinion, Chief Justice John Roberts implied that courts may now apply a decades-old case, *Skidmore v. Swift & Co.* (1944). *Skidmore* does not mandate automatic deference; rather, the level of deference given is determined by several factors, including the thoroughness of the agency's investigation and the validity of its reasoning. Accordingly, an agency's interpretation is given "respect according to its persuasiveness." Under *Skidmore*, courts will be entitled to determine how much deference an agency's interpretation will receive based on the agency's ability to support its position.

## Implications for healthcare organizations

Healthcare organizations operate in a highly regulated environment, with numerous federal departments and agencies, such as the Department of Health and Human Services (HHS), Office for Civil Rights (OCR), Office of the Inspector General (OIG), Centers for Medicare & Medicaid Services (CMS) and Food and Drug Administration (FDA), playing critical roles in interpreting and enforcing healthcare laws.

The fall of *Chevron* may have several key implications for these federal agencies and the healthcare organizations they regulate. Courts will now scrutinize agency interpretations of healthcare laws more rigorously. This means that decades-old regulations may be challenged by healthcare organizations, creating greater uncertainty regarding the application and enforcement of such regulations. Decisions made by HHS, CMS, the OCR, the OIG and the FDA, which were previously given deference, may now be subject to more frequent and varied judicial interpretations. For example, in recent months we have seen guidelines, opinions and bulletins released from HHS and the OCR providing their interpretations of the Health Insurance Portability and Accountability Act's (HIPAA) application to emerging technologies such as artificial intelligence (AI). These interpretations will now hold less weight and the agencies will be required to show evidence of their investigations and expertise on a particular subject matter, per *Skidmore*.

Many healthcare organizations, such as the American Heart Association (AHA), filed amicus briefs with the U.S. Supreme Court urging it to maintain *Chevron* and trust in the subject matter expertise of the federal agencies. Commenting on the ruling, the AHA stated, "[L]arge health programs such as Medicaid and Medicare, as well as issues related to the [Federal] Food, Drug, and Cosmetic Act, are extremely complex, so it is key that decisions about how to interpret and implement relevant laws are made by experts at government agencies."

With less deference to agency "expertise," the stability and predictability of healthcare regulations could be compromised. The ruling also indicates that interpretations will now be focused more on the judicial and evidentiary records. The ruling invites an increased level of litigation, as healthcare organizations may now be emboldened to challenge federal agencies' administrative interpretations.

As we have seen with HHS' recent AI and web-tracking policies, agencies have traditionally used their interpretative authority to adapt policies to address emerging healthcare issues. The loss of *Chevron* deference could hinder agencies' ability to respond swiftly and effectively to new challenges, potentially slowing the implementation of important health policies and innovations. The *Loper Bright* ruling may call the interpretation of complex laws such as HIPAA and the Affordable Care Act back into question, with courts playing a larger role and questioning agencies' persuasiveness and diligence.

## Conclusion

The Supreme Court's decision to overturn *Chevron* represents a significant shift in the balance of power between the judiciary and administrative agencies. For healthcare organizations, this change introduces a new era of legal and regulatory uncertainty. While the full impact of this decision will become clearer over time, healthcare organizations must remain vigilant, adapt to the evolving legal landscape and seek legal counsel to navigate the complexities of this new regulatory environment.

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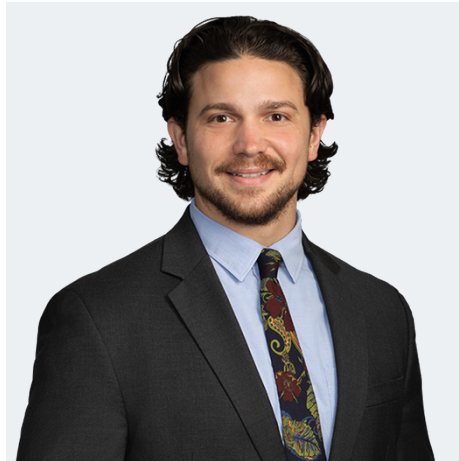
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