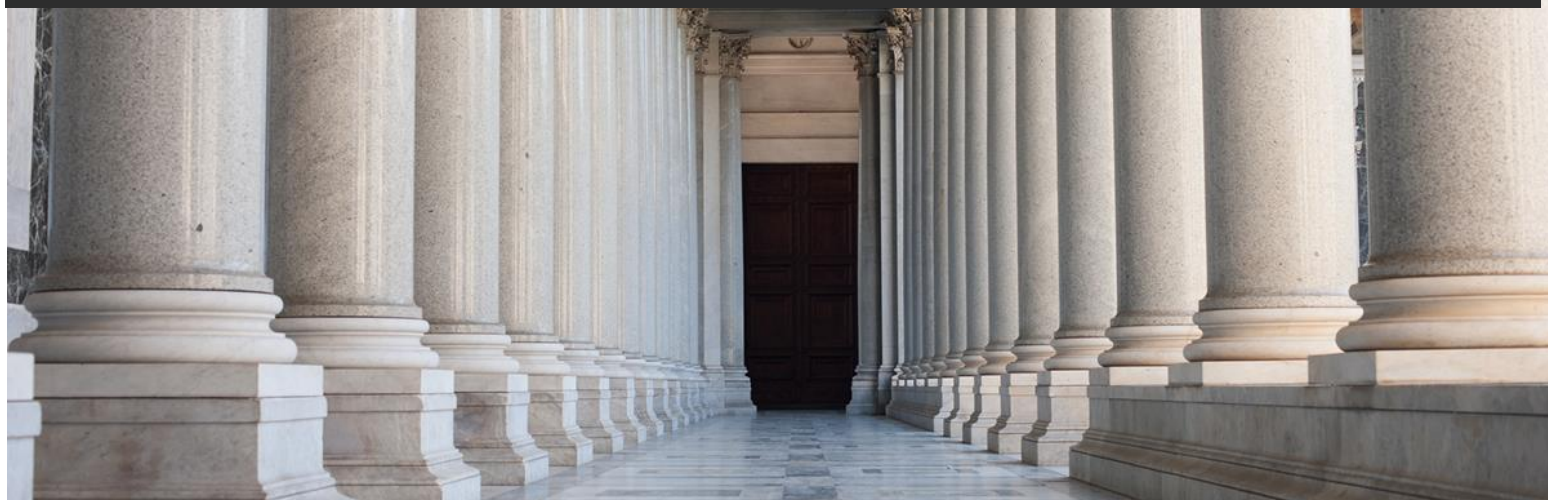


**Alert | Federal Regulatory & Administrative Law/
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Landmark Rulings in *Jarkesy* and *Loper Bright* to Reset Course of Federal Administrative Law

A hedge fund manager and a fisherman walk into a 'bar' . . . and change the health care industry for a generation. Any active litigation against a federal agency is due for a post-Chevron checkup.

This week, the U.S. Supreme Court handed down two landmark rulings that will reset the course of federal administrative law, and the health care industry's regulation by agencies like the FDA and CMS, for a generation. In the esoteric but impactful world of administrative litigation, a tectonic shift has occurred.

The first case, *SEC v. Jarkesy*, changes the way health care providers bring administrative challenges to agency enforcement actions that are presided over by administrative law judges (ALJs). The second case, *Loper Bright Enterprises v. Raimondo*, transforms the way a court may defer to any agency's interpretation of ambiguous language in a statute.

SEC v. Jarkesy

In *Jarkesy*, the Court ruled that the Securities and Exchange Commission administrative proceedings against hedge fund manager George Jarkesy violated his constitutional rights. The Court found that the SEC's use of ALJs to adjudicate enforcement actions infringed on the Seventh Amendment right to a jury trial. It also ruled that this process violated the non-delegation doctrine, which restricts Congress from transferring its legislative powers to executive agencies without clear guidelines.

Additionally, the Court held that the SEC's structure, where ALJs are insulated from presidential oversight by multiple layers of tenure protection, violated the Constitution's separation of powers. This decision will apply across all federal agencies that rely on the hundreds of ALJs adjudicating administrative disputes against agency enforcement actions. Now, an agency's ability to use internal adjudication measures like ALJs is significantly curtailed, but identifying the metes and bounds of an ALJs' authority will play out in additional cases for years to come.

Jarkesy's Impact on the Health Care Industry

Health care providers are all too familiar with the ALJ adjudication processes, which applies in a wide array of Medicare programs. From routine reimbursement appeals under Medicare Part B to fraud and abuse enforcement activities initiated by Uniform Program Integrity Contractors with the Centers for Medicare & Medicaid Services (CMS) and more, *Jarkesy* will disrupt this complex and nationwide framework.

First, *Jarkesy* suggests that Medicare administrative appeals before an ALJ may violate the Seventh Amendment right to a jury trial and the non-delegation doctrine, which prevents Congress from transferring its legislative powers to another branch without adequate guidelines. Stakeholders can anticipate stricter judicial scrutiny and potential restructuring of these administrative appeals processes. Businesses currently going through Medicare administrative appeals should immediately connect with counsel who can advise on whether the ALJ proceeding remains constitutional.

Second, *Jarkesy* highlights the potential for increased judicial oversight over such administrative appeals. Health care providers, frequently challenged by costly and complex administrative appeals with stiff penalties for even minor failures, may find new grounds to challenge the not only the constitutionality of ALJ enforcement proceedings, but the issuance of Civil Monetary Penalties (CMPs) under an ALJ's watch. This could lead to a shift where more cases are heard in federal courts rather than administrative tribunals, offering providers additional procedural protections and possibly more favorable and timely outcomes.

Third, the *Jarkesy* ruling may prompt legislative and regulatory changes to align CMS's current administrative appeals processes with constitutional requirements. This will involve a complicated, extended, and lengthy interplay between the U.S. Department of Justice, the U.S. Department of Health and Human Services (HHS) Office of the General Counsel for the CMS Division, the HHS Office of Inspector General, the HHS Office of Medicare Hearings and Appeals (OMHA), the Departmental Appeals Board (DAB), and key agency staff at CMS itself, who all will need to revisit their adjudication processes to ensure compliance with the Court's decision. This exercise will almost certainly involve changes in how cases are assigned to ALJs, the role of juries in administrative proceedings, and the overall structure of administrative enforcement actions, potentially leading to more transparent and accountable practices on the part of federal contractors.

Fourth, the decision in *Jarkesy* will almost certainly impact the speed and timing of regulatory enforcement. Depending on the type of appeal at issue, administrative adjudications may present faster or slower opportunities for complaining parties to resolve than federal courts. Administrative appeal backlogs, to which OMHA is no stranger, may increase in some programs and decrease in others, which will affect the timely enforcement of health care standards and compliance with regulations.

Finally, *Jarkesy* reinforces the role of constitutional safeguards in administrative law, emphasizing due process and fair trial rights, even under the Administrative Procedure Act. The community of health care

providers, often facing significant penalties and reputational risks in regulatory actions, may benefit from the increased emphasis on their rights. This could lead to a more balanced approach where providers have a fairer and more robust opportunity to defend themselves against agency allegations and actions, especially those issued by an alphabet soup of federal contractors.

Loper Bright Enterprises v. Raimondo

In perhaps the most hotly anticipated decision of the 2024 Term, *Loper Bright* asked the U.S. Supreme Court to reject and reshape the balance of power between executive agencies and the federal judiciary that has existed since 1984. The Court's decision involved a challenge to the National Marine Fisheries Service (NMFS)'s interpretation of the Magnuson-Stevens Fishery Conservation and Management Act, particularly the requirement that commercial fishermen pay for at-sea monitoring. The petitioners argued that the NMFS overstepped its authority where the underlying statute was silent on these requirements. The lower courts upheld the agency's interpretation based on *Chevron* deference. *Chevron* deference—a longstanding doctrine of administrative law—required courts to “defer” to reasonable agency interpretations of ambiguous statutes. But the issue in this case was whether statutory *silence* on specific powers *implies ambiguity*, which would then trigger deference. The Court's review was limited to this narrow question, making it a crucial test of the longstanding *Chevron* precedent.

In its decision, the Court ruled that the *Chevron* deference doctrine did not apply in this instance, as the statutory language did not indicate ambiguity that would justify deference to the NMFS's interpretation. The Court emphasized that deference is inappropriate when agencies infer expansive powers from statutory silence, thereby setting a stricter standard for agency interpretations of laws. This outcome will have broad implications, affecting not only environmental regulations but also all regulated industries operating in the United States.

Loper Bright's Impact on the Health Care Industry

The Supreme Court's decision in *Loper Bright* will have significant implications for HHS, the Food & Drug Administration, and CMS, which together regulate virtually every aspect of the U.S. health care system. Because HHS and CMS frequently rely on *Chevron* deference to defend their interpretations of ambiguous provisions of the Medicare and Medicaid Acts, *Loper Bright* will fundamentally disrupt CMS's interpretive authority that previously existed under *Chevron*.

First, *Loper Bright* emphasizes that statutory silence or ambiguity does not automatically warrant deference to an agency's interpretation. This means that reviewing courts will scrutinize CMS's interpretations more rigorously, requiring clear statutory authorization for its actions. This may lead to more frequent legal challenges against CMS decisions and policies, as the regulated communities of hospitals, physicians, nurses, clinical laboratories, durable medical equipment suppliers, and even States, now have stronger grounds to contest CMS's interpretations in court.

Second, *Loper Bright* reframes the rulemaking environment. Without the protection of *Chevron* deference, CMS must be more cautious and precise in its notice-and-comment rulemaking processes to ensure its regulations withstand judicial scrutiny both in substance and in procedure. The necessity of taking defensive approaches to rulemaking may also slow the implementation of new policies and require more detailed justifications and documentation to support CMS's interpretations of the statutory authorities the agency invokes.

Third, *Loper Bright* may prompt Congress to draft clearer, more comprehensive, and more detailed legislation affecting the Medicare and Medicaid programs. Indeed, this may be one of the only options

available to limit the number of statutory ambiguities that CMS must interpret, an exercise that now carries greater litigation risk. Lawmakers in Congress may also need to explicitly outline the scope and limits of CMS's authority to avoid disputes over statutory interpretation, potentially leading to more prescriptive and onerous health care laws.

Fourth, *Loper Bright* may impact future policy changes and new initiatives by CMS, such as those involving alternative payment models, quality reporting requirements, and national and local coverage determinations. Courts may be less willing to defer to CMS's expertise and discretion, requiring stronger evidence and justification for the agency's actions. This could particularly affect innovative or experimental programs housed at the Center for Medicare and Medicaid Innovation that rely on broad interpretive authority.

Finally, in the long term, the *Loper Bright* ruling may lead to a more restrained and conservative approach by CMS in its regulatory activities. The agency might prioritize activities with crystal clear, plain language statutory authority and avoid policy areas feature more ambiguous statutory authority. Put into action, this may limit CMS's ability to address new and innovative models of care, and incentivize the agency to retreat to its legacy models of health care delivery.

The seismic shifts that occurred in the U.S. Supreme Court this week will send a shockwave through the healthcare industry and the agencies that regulate it. The balance of power between federal agencies in Washington, D.C. and regulated entities no longer favors the agencies in the same way. Now, providers and businesses should envision a new landscape of judicial review available to those that must challenge adverse agency action. Business in the healthcare industry that are either currently engaged in disputes with CMS or its contractors, or that anticipate issues related to new or amended regulations, should contact experienced counsel to discuss how these landmark decisions in the Supreme Court affect them.

Greenberg Traurig's Washington, D.C., location features several attorneys with extensive backgrounds in these key government agencies and critical experience in federal administrative litigation.

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