SCOTUS Rejects Chevron Deference: Healthcare Industry Implications

On June 28, 2024, the U.S. Supreme Court issued a seismic decision explicitly overruling the "*Chevron* doctrine," which will limit the ability of federal agencies to rely on their own interpretation of the laws they administer.¹ Under the *Chevron* doctrine, more commonly referred to as *Chevron* deference, courts were mandated to uphold a federal agency's interpretation of a statute as long as it was reasonable.² This Health Capital Topics article discusses the *Chevron* doctrine, the Supreme Court's decision, and the impact of this ruling on the healthcare industry.

Chevron deference is a legal test established in the 1984 Supreme Court case, Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.³ In this case, the Court ruled that when federal law is ambiguous, and a federal agency issues a regulation interpreting the ambiguity, courts must defer to the agency's interpretation.⁴ Under Chevron deference, courts first assessed whether Congress directly addressed the question at issue – if so, courts relied on Congress's intent; if not, courts deferred to the federal agency's interpretation of the issue. While the Supreme Court itself has rarely relied on Chevron deference, the framework was essential to U.S. administrative law for nearly 40 years and utilized by lower courts in over 18,000 judicial opinions.⁵

The Supreme Court's June 2024 ruling addresses two cases, *Loper Bright Enterprises v. Raimondo* and *Relentless, Inc. v. Department of Commerce*.⁶ In both cases, commercial fishing companies challenged the Department of Commerce's rule that held fishing vessels responsible for the cost of federal observers used to monitor potential overfishing.⁷ The question at issue before the Court was limited to "whether *Chevron...*should be overruled or clarified."⁸

Chief Justice John Roberts delivered the Court's majority opinion, with Justices Thomas, Alito, Gorsuch, Kavanaugh, and Coney Barrett issuing concurring opinions. In the majority opinion, Chief Justice Roberts asserted that *Chevron* deference is inconsistent with the Administrative Procedure Act (APA), a federal law that dictates federal agency procedure and instructs how courts can review federal agency actions. The Chief Justice stated that "agency interpretations of statutes—like agency interpretations of the Constitution—are *not* entitled to deference." The Chief Justice also stated that under the APA, it "remains the responsibility of the court to decide whether the law means what the agency says."

Any suggestion that federal agencies are better equipped to determine ambiguous federal law than courts was rejected by the Court, even when the ambiguous federal law involves scientific or technical questions in which the agency has expertise, reasoning that "Congress expects courts to handle technical statutory questions, and courts did so without issue in agency cases before *Chevron*." ¹³ While the majority opinion made clear that courts should not defer to agency interpretation for an ambiguous statute, courts can consider the interpretation if it falls within the agency's purview as explicitly granted by Congress. ¹⁴

Justice Gorsuch's concurring opinion added that "the Court returns judges to interpretive rules that have guided federal courts since the Nation's founding." Justice Gorsuch also stated that "all today's decision means is that, going forward, federal courts will do exactly as this Court has since 2016, exactly as it did before the mid-1980s, and exactly as it had done since the founding: resolve cases and controversies without any systemic bias in the government's favor." Justice Thomas's concurrence argued that the *Chevron* doctrine is also a violation of the Constitution's division of power among the federal government's legislative, judicial, and executive branches, and "Chevron deference [permitted] the Executive Branch to exercise powers not given to it." 17

Justice Elena Kagan filed a dissenting opinion with Justice Sonia Sotomayor. Justice Ketanji Brown Jackson joined with dissent on the *Relentless* case only;¹⁸ she was recused from *Loper Bright* due to having heard oral arguments in the case during her time on the bench of the U.S. Court of Appeals for the D.C. Circuit.¹⁹ Justice Kagan expressed concern that the Court's decision would create a "jolt to the legal system," and that "Congress and agencies alike have relied on *Chevron*—have assumed its existence—in much of their work for the last 40 years."

Justice Kagan also expressed skepticism at the assertion that overturning *Chevron* deference would not call previous decisions into question, stating that "[c]ourts motivated to overrule an old Chevron-based decision can always come up with something to label a 'special justification."²¹ Justice Kagan reprimanded her colleagues, stating that "in one fell swoop, the majority today gives itself exclusive power over every open issue—no matter how expertise-driven or policy-laden—involving the meaning of regulatory law. As if it did not

have enough on its plate, the majority turns itself into the country's administrative czar."²²

Impact on Healthcare

The dismantling of *Chevron* deference is expected to place significantly more scrutiny on executive agencies such as the Department of Health and Human Services (HHS), which operates federal healthcare programs such as Medicare and Medicaid, and their ability to implement omnibus laws passed by Congress.²³ The likelihood of agency regulations being overturned by courts will increase, and these decisions will incentivize litigants to challenge undesirable agency regulations in court.²⁴

The ruling is expected to have a wide-ranging impact on the healthcare industry, particularly in the following areas:

- Administration of Medicare and Medicaid: HHS and the Centers for Medicare and Medicaid Services (CMS) may encounter issues in the administration of Medicare and Medicaid if Congress refines the statutes related to the two programs and/or expands the agencies' authority. Ambiguous language in the Medicare and Medicaid regulations would likely need to be addressed in order to decrease the (high) likelihood of legal action challenging the agencies' statutory interpretations.
- Reimbursement of Medicare: When HHS and its agencies made major changes in regard to prescription drugs, hospital, and physician reimbursement, or introduced new requirements for Medicare coverage, *Chevron* allowed courts to provide agencies with wide latitude, and for the agencies to remain largely protected from legal challenges. Post-decision, providers may have more flexibility to challenge HHS on reimbursement issues (e.g., cuts to physician reimbursement, changes to outpatient and inpatient payment systems).
- Medicare and Medicaid Coverage Disputes: When HHS or CMS made a determination as to whether an item or service qualified for Medicare or Medicaid coverage, courts typically would give weight to the agencies' understanding of their statutes. Post-decision, the number of coverage disputes are likely to increase, and the courts will wield the power to resolve such disputes de novo.
- Fraud and Abuse Law: The healthcare industry is heavily regulated by fraud and abuse laws such as the Anti-Kickback Statute (AKS), Stark Law, the False Claims Act (FCA), and the Civil Monetary Penalties Law. Violators of these laws face civil and criminal penalties, as well as exclusion from federal healthcare programs such as Medicare and Medicaid. For years, HHS and its agencies have interpreted these statutes through the regular issuance of updated/revised regulations and guidance (e.g., Special Fraud Alerts & Advisory

- Opinions). Post-decision, providers' compliance and litigation strategies may change, with enforcement actions potentially decreasing due to uncertainty as to whether a court will uphold agency interpretation.²⁵
- Food and Drug Administration (FDA) Decision Making: Under the Food, Drug, and Cosmetic Act (FDCA), the FDA has authority to oversee the safety of cosmetics, medical devices, food, and drugs. *Chevron* deference allowed for the agency to rely on evidence-based decisions regarding medical products and drugs, despite the FDCA's ambiguous language. Post-decision, courts may still defer to the FDA, but the number of appeals will likely increase due to the possibility that courts may choose to interpret ambiguities differently from the FDA.
- Long Term Care Survey and Certification Enforcement: Skilled nursing facilities and other nursing facilities receiving Medicare or Medicaid reimbursement are routinely surveyed by federal and state authorities, and any noncompliance can lead to a plethora of penalties. Post-decision, these compliance regulations may be more easily challenged by facilities.

With *Chevron* deference overruled, the authority to interpret statutes and regulations will shift from federal agencies and legal challenges to all agency actions are likely to increase.²⁶

Post-decision, regulatory ambiguities will not be resolved by subject matter experts (such as federal agencies), but by the courts and Congress. Congress will still retain the ability to delegate the task of regulation development to specific administrative agencies; however, regulations from these agencies may now be reviewed by courts without any deference. This major shift in legal framework is expected to drastically increase federal litigation, with every single federal agency's decision having the potential of being challenged in court.

The change in deference to federal agencies could lead to scenarios where courts make inconsistent determinations across the U.S., which will create circuit splits.³⁰ The *Loper* decision may also lead to difficulties for federal agencies that are trying to expand the scope of certain statutes and reduce the likelihood of new agency requirements.³¹ While this ruling will affect all industries regulated by federal agencies, the effect on healthcare will be significant due to the complex regulatory environment in which providers operate.

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