The Supreme Court's Reversal of the *Chevron* Doctrine and its Impact on Health Law

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On June 28, 2024, the Supreme Court dealt a blow to federal administrative agencies in its decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S._(2024),[1] in which the Court overruled long-standing precedent that courts relied upon in challenges to agency decisions. While the reach of the *Loper Bright* decision reaches all regulated industries, this Client Alert will focus on its impact to the healthcare industry.

The *Chevron* Doctrine Explained

For many years, federal courts have relied on a legal doctrine known as "*Chevron* deference" to interpret ambiguous laws passed by Congress. This principle, established by a 1984 Supreme Court case, *Chevron U. S. A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), allows courts to defer to the expertise of government agencies in their interpretation of the laws they are responsible for enforcing. Under *Chevron*, courts employ a two-step process to determine the propriety of agency action: first, determining if the law is ambiguous, and if so, evaluating whether the agency's interpretation is reasonable.

The *Chevron* doctrine's deference played a crucial role in numerous judicial decisions in its 40-year existence, cited more than 19,000 times, making it one of the most referenced cases in U.S. legal history. From a healthcare perspective, the doctrine was regularly used to uphold agency decisions under various statutes. For instance, courts deferred to the Department of Health and Human Services (HHS) and its various agencies, including the Centers for Medicare & Medicaid Services (CMS), the Food and Drug Agency (FDA), the Centers for Disease Control and Prevention (CDC) and the Office of Civil Rights (OCR) in cases involving the laws and regulations governing Medicare, Medicaid and Children's Health Insurance Program (CHIP), the Health Information Portability and Accountability Act (HIPAA) and

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the Food, Drug and Cosmetics Act (FDCA). While not part of HHS, the *Chevron* doctrine is also cited in cases involving social security benefits under the Social Security Act giving deference to the Social Security Administration (SSA). In short, most decisions related to healthcare services, quality and protections afforded under federal law, the *Chevron* doctrine was likely cited to uphold the agencies' decisions.

This precedent allowed agencies with specialized expertise to interpret complex and technical statutes. However, this recent Supreme Court decision reversed this long-standing precedent, mandating that courts must now independently interpret statutes without deferring to agency interpretations. This shift marks a significant change, with potential wide-ranging impacts on regulatory practices in the laws impacting healthcare and elsewhere.

Implications on Health Law

The Supreme Court's decision to overturn the *Chevron* doctrine is likely to have significant impact on regulations interpreting and implementing many of the laws relating to healthcare. With this change, government agencies' interpretations under the HHS (see a complete list here) will be subject to independent judicial review.

Rulemaking Practices/Increased Litigation

This ruling will likely trigger a surge in lawsuits challenging agency interpretations of current and future laws, as parties see new opportunities to contest regulations. In response, agencies like the FDA and CMS will likely change how they write regulations. To avoid legal disputes, they will need to create more detailed and specific rules. Outside stakeholders and interest groups may increase lobbying efforts in Congress, advocating for more precise statutes that instruct agencies on how to implement the law, thus reducing ambiguity and the need for court intervention.

Moreover, the Supreme Court's decision insists it doesn't overturn past rulings that upheld regulations based on *Chevron* deference. However, it indicates that reliance on *Chevron* alone is insufficient to justify keeping those regulations. Thus, if the other factors justifying past decisions, like the quality of reasoning, are weak, then those regulations could be challenged as hinted by the dissenting opinion in *Loper Bright*. This, along with the recent decision in *Corner Post v. Board of Governors of the Federal Reserve System*, confirms that parties can challenge long-standing regulations within six years of being affected.

Areas Affected by the Ruling

There will be a number of areas affected by this ruling, including:

Medicare Reimbursement: HHS and its associated agencies often limit Medicare reimbursement for certain goods or services. Healthcare providers may now have increased opportunities to contest these decisions, and the courts reviewing the cases will no longer be required to defer to the agency's perspective.

Coverage Disputes: Courts previously deferred to agency interpretations regarding which services qualified for coverage under the Affordable Care Act. With the *Chevron* case precedent overruled, providers and patients may see variations in Medicare and Medicaid coverage depending on how the courts interpret the rules, which could result in more or fewer services being covered compared to CMS's interpretations.

FDA Decisions: The FDA regulates drugs under the FDCA, which often contains ambiguities previously clarified by *Chevron* deference. Overruling the *Chevron* precedent will likely lead to more lawsuits and appeals against the FDA's drug decisions. Courts might independently reinterpret these ambiguities, causing approval delays and creating and possibly causing uncertainty for manufacturers bringing new products to market.

Long-Term Care: Nursing home facilities that participate in Medicare and Medicaid programs undergo evaluations by federal agencies (like CMS) to ensure compliance with regulations. The overruling of *Chevron* will likely lead to increased challenges against regulatory guidance issued by CMS.

Drug Prices: The ability of Medicare to negotiate drug prices, a key provision of the Inflation Reduction Act, could be weakened. Numerous lawsuits have been filed challenging the constitutionality of the Medicare negotiation program. With the reversal of *Chevron*, courts will interpret these rules making it harder for HHS to defend the program based solely on their view.

Fraud and Abuse: Healthcare providers are subject to a myriad of laws, rules, regulations, and guidance that seek to combat fraud, waste and abuse (FWA). Among the most notable being the Anti-Kickback Statute (AKS), the Physician Self-Referral Law (a/k/a the "Stark" Law), the Civil Monetary Penalties Law (CMPL) and the Eliminating Kickbacks in Recovery Act (EKRA). For years, the HHS Office of Inspector General (OIG) and CMS have played a large role in combating FWA through numerous agency-issued guidance, opinions, regulations and policies that courts have relied upon to establish violations of the cited laws. With the elimination of *Chevron* deference, courts may no longer rely on the agency interpretation of these laws in cases that come before them leading to greater uncertainty in the healthcare industry regarding their compliance efforts.

While these are just a sampling of how the *Loper Bright* decision may impact the highly regulated healthcare industry, Butzel will continue to monitor these developments and provide guidance to navigate this evolving landscape effectively.

Implication of State Administrative Actions

While the *Loper Bright* decision addresses federal agency deference, Michigan courts have likewise relied on the *Chevron* doctrine cases involving administrative agency decisions. With the elimination of judicial deference to administrative agencies, the impact can trickle down to state actions involving such issues as professional licensure, state-provided benefits and state oversight. Again, only time will tell as to how the reversal of *Chevron* will affect state agencies, but the likelihood of challenges to state agency deference may increase, leaving providers and practitioners scrambling

to understand what is and is not required of them.

Potential for Legislative Change

The Supreme Court's decision was based on the Administrative Procedure Act (APA). This means that Congress could theoretically rewrite the APA to allow courts to again defer to agency interpretations of unclear laws. However, some concurring justices suggested that such an amendment might not be constitutionally permissible, but most justices did not comment.

For further details on the Court's decisions and their potential impact on your organization, please contact the authors of this Client Alert or your Butzel attorney.

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[1] The Supreme Court's case was a consolidated decision involving the D.C. Court of Appeals' decision in *Loper Bright* (Docket No, 22-451) and the First Circuit's decision in *Relentless, Inc. v. Department of Commerce* (Docket No. 22-1219).

References:

Loper Bright Enterprises v. Raimondo

Brief of *Amici Curiae* American Cancer Society, American Cancer Society Cancer Action Network, National Health Law

What the Supreme Court's "*Chevron* Deference" Ruling Could Mean for Health Care Law

Chevron Overturned: What Does It Mean for Life Sciences Companies?