PUBLICATION

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

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Baker Donelson recently published *Anticipating SCOTUS Ruling on Chevron Deference – What to Know and Five Ways to Prepare* explaining the United States Supreme Court's upcoming ruling which is expected to impact the regulatory interpretation standard established by *Chevron v. National Resources Defense Council* and the deference it affords to federal administrative agencies' interpretations of federal statutes. The Supreme Court ruling is expected to be published any day. Although the cases before the Court involve environmental matters, the impact on the *Chevron* doctrine could affect multiple industries. In this article extension, we will focus on the ruling's potential impacts on the health care industry. Keep reading for an overview of the issues and eight key areas within health care that may face significant disruption if the Supreme Court overturns or modifies *Chevron* deference.

What Does an Overturning/Limitation of *Chevron* Mean?

Under the *Chevron* doctrine, when a statute is ambiguous or silent, a court will generally defer to an agency's interpretation as long as it is reasonable, and Congress has not spoken directly to the issue.

The cases before the U.S. Supreme Court, *Loper Bright Enterprises v. Raimondo* and *Relentless Inc. v. Department of Commerce*, are centered around the management of an Atlantic herring fishery. The question is whether the Supreme Court will uphold *Chevron* deference as it currently stands, or if the Court is going to grant greater authority to judges to use their own discretion and expertise in interpreting ambiguous federal statutes and agency decisions.

The pending ruling could impact the scope of this deference and thereby alter how federal agencies apply their own interpretations of statutes that Congress has passed and tasked those agencies to administer. Health care is one of the most highly regulated industries, and the impact could be significant in a number of ways.

For instance, an amicus brief filed by a coalition of health care entities contended that "[o]verruling *Chevron* would have enormous impact on the administration of federal programs – including Medicare, Medicaid, and CHIP – that are crucial to public health." Additionally, the health care industry could see a delay or chill in federal agencies' rulemaking processes and an increase in litigation challenging those rules and regulations.

Litigation Rise

The *Chevron* ruling could ultimately result in a plethora of litigation challenging federal rules and regulations governing health care. A ruling that either overturns *Chevron* or results in reduced agency deference could provide a path for parties to challenge an agency's prior rulemakings to the extent they were based on interpretations of ambiguous statutes. Instead of deferring to agencies' interpretations of ambiguous statutes, federal courts may give plaintiffs the opportunity to challenge those interpretations and review competing interpretations using the court's own analysis. A court could substitute an agency's interpretation of a

regulation that relies on what the agency thinks is necessary to fulfill its mission for a court's interpretation that applies traditional interpretation methodologies like the rules of statutory construction.

Agencies under the U.S. Department of Health and Human Services (HHS), such as the Centers for Medicare and Medicaid Services (CMS) (see a list of such agencies here), have a complex web of rules, regulations, and other guidance (such as advisory opinions and manuals). Many argue these agency actions surpass the authority granted by Congress for oversight of the federal government's taxpayer-funded health care system. Challengers have often argued that this discretion allows executive branch agencies essentially to perform legislative functions without being subjected to appropriate judicial review, allows agencies to impact the rights of parties without following the requirements of traditional rulemaking, and further denies due process to parties. The deference, challengers argue, allows an agency to apply its own interpretation to rules, without judicial review, in disputes between the agency and private parties. If the Supreme Court limits *Chevron* in a substantial way, health care providers, their associations, and other private parties could challenge regulations and other determinations by agencies and receive a more fulsome, independent review by the judiciary. In turn, the government is concerned that, among other impacts, limitating or overturning *Chevron* could result in providers and associations choosing not to comply with rules, regulations, and guidance because they believe a court may overturn or decline to enforce them.

Eight Areas of Health Care the Ruling Could Impact

There are many substantive areas where *Chevron* deference is implicated in health law. Below are several areas of health care that are likely to be meaningfully impacted if the Supreme Court's ruling alters the current doctrine.

1. Medicare Reimbursement

One of the areas most likely to experience a major shift if *Chevron* is overturned is Medicare reimbursement. Medicare reimbursement appeals and cases frequently implicate *Chevron*. Typically, when HHS and its sub-agencies make changes limiting reimbursement for hospitals or prescription drugs or adding new coverage requirements (as explained below), *Chevron* is often relied on to support the agency's position on a particular reimbursement question. Without the deference afforded to agencies under *Chevron*, providers may have more opportunities to challenge reimbursement positions held by the agency.

2. Medicare and Medicaid Coverage Disputes

In determining whether a certain item or service qualifies for Medicare or Medicaid coverage, federal courts have historically given great weight to HHS's and CMS's reading of applicable statutes, such as the Social Security Act and the Affordable Care Act. Oftentimes, disputes over coverage turn on the meaning of certain statutory words and phrases. For instance, according to Section 1862(a)(1)(A) of the Social Security Act, items and services only qualify for Medicare coverage if they are "reasonable and necessary for the diagnosis or treatment of illness or injury." CMS has adopted rules and regulations that define the scope of coverage, and courts have afforded *Chevron* deference to these regulatory interpretations in coverage disputes. If *Chevron* deference is overturned or curtailed, the quantity of coverage disputes is likely to increase, as beneficiaries and their advocates will look to courts to interpret the statutory language in their favor.

3. Administration of Medicare and Medicaid

If agencies are no longer given deference in interpreting ambiguous statutes, HHS and CMS may face difficulties in administering Medicare and Medicaid as tasked by Congress. To ensure the agencies' interpretations are enforced, Congress would likely need to refine the Medicare and Medicaid statutes to expand the scope of agency authority and address any existing ambiguous language by memorializing the

agencies' interpretations. Without discretion given to the agencies, health care organizations and beneficiaries would have a greater chance of success in bringing litigation against the agencies.

4. Nondiscrimination Under the Affordable Care Act

Section 1557 of the Affordable Care Act prohibits any health program or activity that receives federal assistance from discriminating on the basis of race, color, national origin, sex, age, or disability. The past three presidential administrations have promulgated regulations interpreting this nondiscrimination requirement. In fact, recently on May 6, 2024, HHS, CMS, and the Office for Civil Rights published a Final Rule interpreting Section 1557, particularly as it applies to sexual orientation and gender identity and Limited English Proficiency requirements. If *Chevron* deference is disrupted, agencies' interpretations like that in the May 6 Final Rule will be vulnerable, and ambiguous language in Section 1557 will be left to the interpretation of the courts.

5. FDA Decision Making Under the Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act (FDCA) gives the Food and Drug Administration (FDA) authority to oversee the safety of food, drugs, medical devices, and cosmetics. The FDA relies on deference granted by *Chevron* to make evidence-based decisions regarding drugs, medical devices, and other medical products. In order to make scientifically supported decisions throughout the life cycle of a drug or medical device, the FDCA's statutory scheme includes broad language that is inherently ambiguous. An amicus brief filed by the Democracy Forward Foundation outlines the possible implications of a *Chevron* disruption in relation to FDA regulations. Without discretion under *Chevron*, the FDA's regulations and expectations are likely to be challenged more often. Even if courts still ultimately choose to rely on the FDA interpretations, the number of appeals will increase due to the new possibility that a court could choose to interpret ambiguities without deference to the FDA.

6. Social Security and Disability Benefits

In cases pertaining to Social Security and disability benefits, oftentimes statutory language is challenged on the basis that it is ambiguous. In the past, several cases have implicated *Chevron*, and courts have provided discretion to the Social Security Administration (SSA). In cases where disability benefits have been revoked, there is often debate as to whether the statutory language of the Social Security Act is ambiguous. Historically, the SSA has received deference in most situations regarding disability benefits. However, if *Chevron* is disturbed, there will be a broader opportunity for those who lose benefits to challenge the ruling, and courts may have the discretion to rule on those situations.

7. Health Care Fraud and Abuse Laws

The health care industry is heavily regulated by fraud and abuse laws, such as the Anti-Kickback Statute (AKS), Stark Act, False Claims Act, and Civil Monetary Penalties Law. Violation of these laws can result in severe sanctions, including civil and criminal penalties and exclusion from federal health care programs. For decades, HHS, CMS, and the Office of Inspector General (OIG) have interpreted these statutes through regulations and guidance, including Special Fraud Alerts, OIG Advisory Opinions, and Bulletins. Federal courts have upheld agencies' interpretations of these fraud and abuse laws under *Chevron* in enforcement actions. If the *Chevron* framework is modified, compliance and litigation strategies in this space will likely change. For instance, providers may be more hesitant to submit self-disclosures to the OIG for possible violations if courts are less likely to defer to agencies' policies, rules, and guidance. Similarly, government enforcement actions, investigations, and whistleblower suits may decrease due to the uncertainty as to whether a court would uphold agencies' interpretations of these fraud and abuse laws.

8. Long Term Care Survey and Certification Enforcement

Health care providers of all categories are subject to increasingly rigorous scrutiny and enforcement penalties for asserted violations of survey, certification and enrollment regulations. This is particularly apparent for skilled nursing facilities and nursing facilities under Medicare and Medicaid, as they are not eligible for certification by

CMS on the basis of "deemed status" accreditation but rather are directly surveyed by federal and state agencies. Such asserted noncompliance not only can lead to termination of provider status but can cause other penalties to be imposed or provider enrollment affected. Disputes and appeals can arise depending on the application of CMS subregulatory guidance but such subregulatory guidance must be supported by law or regulation. A change in the Chevron standard of review may not only affect the validity of regulations not clearly supported by the related statute. Subregulatory guidance based on a regulation not entitled to judicial deference and found to be invalid would likewise be subject to challenge.

Other Areas of Potential Impact

Other areas within the health care industry which could be affected by the Supreme Court's ruling include, but are not limited to, Medicare drug price negotiations under the Inflation Reduction Act, surprise medical billing rules under the No Surprises Act, preventive health care services under the Affordable Care Act, rules and regulations regarding the pandemic (such as vaccines and public health), and patients' data protection and privacy under the Privacy Rule of the Health Insurance Portability and Accountability Act.

Baker Donelson's Health Law Group has deep experience in all of the above areas and with federal rules and regulations. Our attorneys are available to advise you regardless of how the Court may rule. If you have questions about how your organization can navigate preparing for the Supreme Court's ruling, please reach out to McKenna S. Cloud, Thomas H. Barnard, or your Baker Donelson counsel.

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