POLSINELLI

Publications

August 7, 2024 • Updates

Top Questions Health Care Providers Should Consider in a Post-Chevron World – A Polsinelli Round Table Discussion

Health Care is one of the most regulated industries in the country, and for many years, one of the key administrative agencies overseeing health care in the United States, the Department of Health and Human Services' ("HHS") Centers for Medicare & Medicaid Services ("CMS"), has enjoyed broad authority to regulate health care under the "*Chevron* doctrine." Under this doctrine, CMS and other federal agencies were granted broad discretion to interpret and implement the law, thus allowing them to drive how care is delivered and paid for in the United States. It was difficult for providers to successfully challenge agency rulemaking in federal court, even if they thought the agency's interpretation of the law was incorrect. The Supreme Court's dismantling of *Chevron* doctrine will have a significant impact on health care providers, which we may begin to see as we move into CMS's annual rulemaking cycle.

The Supreme Court's decision to overturn *Chevron* was expected, but it is still too soon to truly understand the full impact of the decisions on the health care industry. A round table of attorneys and policy advisors from Polsinelli's Health Care, Public Policy and Government Investigations Department discussed the potential short and long-term implications of the decision and offer the following insights for health care providers across this ever-changing industry for navigating the web of statutes, rules and other sub-regulatory guidance post-*Chevron*.

1. What do the *Loper/Relentless* Decisions Change for Health Care Organizations in the Short-Term? Has CMS's Authority to Regulate Health Care Gone Away or Been Substantially Limited?

"Likely, not. Many of the health care regulations are based on clear statutory language and will continue to give providers the rules for the road from a compliance standpoint. More controversial rules – like mental health parity, payment cuts, surprise billing, antidiscrimination, etc. – may be further delayed or even tabled for the short term while we learn more about how these challenges will be viewed by the courts. To the extent health care providers are struggling with a rulemaking negatively impacting them, it is worth beginning to evaluate whether challenging it may be warranted." – Bragg Hemme

"CMS's authority to regulate today is just like yesterday and probably tomorrow. Without a

Related People

- Bragg E. Hemme
- Jennifer L. Evans
- Meredith A. Duncan
- Sara Avakian
- Neal D. Shah
- Michael M. Gaba
- Joshua D. Arters
- ILIANA L. PETERS
- Kathleen Snow Sutton
- Julius W. Hobson, Jr.
- Ronke Fabayo

Related Capabilities

- Health Care
- Public Policy
- Post Chevron Educational Resources & Updates

challenger to a rule, any rule continues unchanged – at least for the short-term. We have already seen; however, some regulated entities challenge a particular rule to a federal court and get some immediate regulatory relief. Members of Congress who want to see large scale changes to regulatory authority may well pursue identification of rules that were upheld in lower courts citing Chevron with an eye towards vitiating those rules with broad Congressional action. There are thousands of such cases and potentially impacted rules." – Jennifer Evans

"Where the crux of *Loper Bright* unravels the courts' existing practice of deferring to regulators' interpretation of a statute that is unclear or ambiguous, we can expect to see increased litigation that challenges agency action arguing that the foundational law for such action was ambiguous and the agency has exceeded its statutory authority. It is unlikely we will see any change in regulator action or regulatory enforcement unless and until courts begin to overturn agency action on the basis that a statute is ambiguous and the agency that interpretated the statute was incorrect. We can also expect to see increased legislation explicitly delegating more authority to agencies." – Meredith Duncan and Sara Avakian

2. What are Some Specific Areas of Health Care Regulation that may be Impacted?

Health Care Fraud, Waste, and Abuse Laws

"The overruling of *Chevron* may have a significant effect on the application of the health care fraud and abuse laws, particularly the Physician Self-Referral Law ("Stark Law") and Anti-Kickback Statute ("AKS"). Over the years, agencies including the HHS Office of Inspector General ("OIG") and CMS have published hundreds of pages of rules, preamble language, and explanatory sub-regulatory guidance regarding the application of these laws. Some of these interpretations favor regulated entities, while others favor enforcers. To the extent *Loper Bright* represents a fundamental change in the role of agencies in clarifying or refining the scope and effect of statutory language, these implementing regulations and, thus, some longstanding health care industry practices could be impacted." – Neal Shah

Reimbursement

"Coverage and payment rules from CMS (Medicare and Medicaid) and DHA (TriCare) may be ripe for attack. It will be interesting to see if the agencies are able or willing to engage in active negotiations to avoid or settle litigation that they did not face with *Chevron* deference." – Jennifer Evans

"I anticipate that many of the routine Medicare reimbursement-related rulemakings (e.g., IPPS, OPPS, Physician Fee Schedule) will continue as they have in the past. Certain aspects of those rules or any controversial rulemakings may now be up for challenge. For instance, rules related to Disproportionate Share Hospitals have already been challenged since the *Loper Bright* decision. Any type of payment cut or agency effort to rein in health care costs, like Medicare drug pricing rules, surprise billing, mental health parity will also be closely scrutinized and likely challenged." – Bragg Hemme

FDA

"Immediate impact is likely to be felt by the Lab Developed Test rule FDA is trying to finalize. Congress tried, but failed, to give the FDA statutory authority in this space via the VALID Act. The FDA went ahead and went through the rulemaking process in one year. This was lightspeed for the FDA. The rule was challenged prior to the reversal of

Chevron. I expect to see the plaintiff amending their complaint now." – Michael Gaba

Surprise Billing

"I expect the *Loper/Relentless* decisions will impact the continued rollout of the regulations implementing the No Surprises Act. Since the law went into effect in 2022, regulations and guidance implementing the No Surprises Act have been vacated following challenges under the Administrative Procedures Act on four separate occasions – and that was under the prior *Chevron* standard, which of course was more deferential to agency decisions. But there are more rules that the Agencies are expected to issue – both as a result of the prior lawsuits and as part of their ongoing obligation to implement the law – that will have a significant impact on how the No Surprises Act functions in practice. These rules will also likely depend on the Departments' interpretation of the No Surprises Act, and such interpretation will now not be afforded the deference that existed in the pre-*Loper/Relentless* landscape." – Josh Arters

3. What Areas of Health Care Regulation are less Likely to be Impacted?

HIPAA

"From an HHS data privacy/security/breach perspective, the *Jarkesy* and *Chevron* decisions will arguably have very little impact unless parties are willing to challenge HHS HIPAA decisions in court. In other words, HHS OCR is proceeding as normal, and will continue to do so, particularly given that the HIPAA Rules were codified and specifically modified by Congress in the HITECH Act in 2009. However, to the extent a client would like to appeal a civil money penalty directly to a district court (*Jarkesy*) or attack a specific provision of sub regulatory guidance post-*Chevron* (*Loper Bright*), we could certainly attempt to do so." – Iliana Peters

Long-Term Care

"Long term care providers are unlikely to see any immediate changes in regulation or enforcement. In most authorizing statutes, Congress delegated authority to CMS to develop and implement conditions of participation, and the guidance that has been provided interpreting those rules. It is unlikely the *Loper Bright* decision will cause CMS to change its survey process or the remedies imposed therefrom. However, any regulation or sub-regulatory guidance, such as the State Operations Manual, which is not expressly authorized by statute or otherwise interprets an ambiguous statute could be ripe for litigation to challenge CMS' authority and/or CMS' interpretation of the statute. To determine whether specific regulations and guidance is subject to challenge will require careful consideration of the Social Security Act and the deference, if any, afforded to CMS for rulemaking." – Meredith Duncan and Sara Avakian

State Licensing & Practice Rules

"Many of the laws that impact health care providers, such as professional or facility licensing requirements and corporate practice of medicine prohibitions, are state laws that are unlikely to be immediately impacted by *Loper Bright*. However, *Loper Bright* may become a catalyst for new challenges to state-level administrative actions, which could create uncertainty related to state agency actions, such as Medical Board rules or guidance." – Kathleen Sutton

4. What Issues Should Health Care Organizations Anticipate in the Long-Term?

“It is unclear if there will be rule/no rule ‘chaos’ for health care organizations. When we think of all of the arrangements that default to ‘compliance with laws’ those provisions may lose meaning and effectiveness if the underlying legal rule-structure is threatened” – Jennifer Evans

“With the rise of litigation to combat potentially adverse rulemakings, we may see disagreement within the provider community to the extent some providers are ’winners’ and others are ‘losers.’ Further, we could see the same rulemaking get treated differently by courts depending on where the rules are being challenged. This will be very difficult to navigate for national providers. Hopefully, this ruling will cause regulatory agencies to take more shareholder feedback in their rulemaking. We will likely see more work needed at a Congressional level, however, if a statute is required for things that have historically been dealt with at a regulatory level, causing a slowdown. This will be a challenge, particularly for innovative providers that are changing care models or adopting new technology, for instance. Health care rules often were behind the evolution of health care. Requiring Congressional action may present some opportunities but will not make things move faster.” – Bragg Hemme

“In the long-term, health care organizations should anticipate an increased opportunity to challenge unlawful regulations that run afoul of Congressional action. That is generally a good thing. But a negative consequence of the *Loper Bright* decisions is the likely impact on the agency rulemaking process, and the time it might take for agencies to issue regulations. Agencies are likely to move a bit slower when issuing new regulations in light of the dramatic change to how their rulemaking will be scrutinized by the courts going forward.” – Josh Arters

“It is likely that Congress will carefully craft new statutes and delegate more clear authority to the administrative agencies charged with enforcement. We also anticipate agencies taking more time to carefully craft their rules and guidance to mitigate the challenges that could arise based on these decisions. For providers, this will only further delay an already backlogged process.” – Meredith Duncan and Sara Avakian

“*Loper Bright* creates opportunities for health care organizations to challenge agency actions, but this opportunity comes at the expense of clarity and certainty that came from deference to agencies. The health care regulatory landscape is already complex and ever-changing, but the lack of uniformity that may result from different courts interpreting the same set of rules is going to create further complexity and confusion. The aftermath of *Loper Bright* may create a chilling effect for innovation or growth for health care businesses. Health care organizations will have to be strategic and stay up-to-date on the changing laws to maintain and grow their businesses while navigating this uncertainty.” – Kathleen Sutton

5. What can Health Care Organizations do if a CMS Rulemaking Has a Significant Impact on their Organization?

“If a rule isn’t working and there is a reasonable interpretation that the statue enabling the rule offers a better outcome, it may be time for health care organizations to start their engines and challenge rules that don’t match specific statutory requirements and fundamental principles. For example, think about adequate reimbursement and access to care. Does this reopen a provider’s ability to litigate payment rules that do not ensure access to care? Maybe.” – Jennifer Evans

“When faced with rulemaking that has a significant impact on operations, health care organizations might be presented with an opportunity to work with federal agencies to find a resolution without having to resort to litigation. Now that agencies understand that their

rulemaking may be challenged under a less deferential standard, and, at least for now, most courts have held that a district court may vacate unlawful rules nationally, agencies might be more willing to find more creative and/or individualized solutions to the unique impact their rules might have on a particular health care organization." – Josh Arters

6. Does this Decision Provide a Greater Ability for Health Care Providers to Advocate for Laws and Regulations to CMS and/or Congress?

"Providers have always had the opportunity to make a contribution in the public policy process; *Loper* means it is even more important. Engagement in the public policy process does not guarantee success, but lack of involvement almost certainly means a loss. Both the legislature and agencies may be more open to negotiated laws and regulations. These processes will take longer, however." – Julius Hobson

"Being part of the debate in the US Congress on health care legislation (and any legislation for that matter) is now more crucial than ever. Members of Congress will no longer be able to write laws that are ambiguous, which would give the agency of jurisdiction the authority to legislate through regulatory fiat. Congress now will be required to be more prescriptive in their laws, outlining specifically in statute the intent of the law. Congress currently relies on 'report language' that accompanies legislation, which expresses the legislative intent; however, the report language is not the black letter of the law and more often than not, the agency of jurisdiction ignores report language. Finally, now that the Congress will need to be more prescriptive in its drafting of legislation Congress will be required be even more deliberative in crafting a bill. This will mean that laws will require more consensus to get the bills it works on approved." - Harry Sporidis

"In 2019, when the Supreme Court issued the *Azar v. Allina Health Services* decision, every component in CMS was tasked with reviewing, analyzing, and verifying that all the guidance materials had regulatory and/or statutory support. For a few years after the decision, CMS went through the rulemaking process for any guidance/policy that was not clearly articulated or supported by regulation. Now that the Supreme Court has overturned *Chevron*, CMS will likely conduct a similar exercise to determine all of the policy areas where the law is ambiguous, and the Agency has made the determination on how best to carry out the law. CMS will also likely consult with its legislative arm to work with Congress to clarify such laws. This undertaking will take CMS several years to complete. While CMS is engaged its review, there is an opportunity for health care organizations to engage with CMS to review policy position that result from an ambiguous statute and reconsider a more favorable interpretation on of the law." – Ronke Fabayo