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A New Era in Federal Administrative Law?

Implications of the Supreme Court's Recent Decisions on Children's Hospitals

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Agenda

- **Judicial Scrutiny of Agency Action: Then and Now**
- **Implications for Health Care**
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  - Medicaid Program Operations
  - Medicaid Drug Coverage and 340B
  - Other Key Policies
- **Discussion and Q&A**

Judicial Scrutiny of Agency Action: Then and Now

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Background: Judicial Review of Agency Actions

Under the Administrative Procedure Act (APA), private parties can challenge agency actions in court, including final rules, individual enforcement actions, and certain types of sub-regulatory guidance.

A court will strike down an agency action if *(among other reasons):*

- **The agency exceeded its authority** – i.e., Congress did not authorize the agency to take this particular action.
- **The agency action was "arbitrary and capricious"** – i.e., the agency had the authority to take this action, but didn't do a good enough job explaining and justifying its action.

The Supreme Court's 2023-2024 term included three major decisions that shift the landscape for APA challenges.

All three decisions included vigorous dissents.

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Agency Authority: *Loper Bright Enterprises v. Raimondo* (1/2)

Many statutes contain ambiguities, inconsistencies, or gaps. In those scenarios, it's not clear exactly how far an agency's authority extends. Who should decide how to fill those gaps?

- ***Chevron* Doctrine: Agencies should decide** *(per 1984 decision)*. If a statute is ambiguous, courts should defer to the agency's interpretation as long as it is *reasonable*.
- ***Loper Bright*: Courts should decide.** Even if a law seems ambiguous, the court must decide the single best interpretation of the statute.
  - The court should consider the agency's interpretation, but is not required to *defer* to the agency's interpretation.
  - However, **a court *should* defer if Congress *expressly* delegates policymaking authority to the agency**. (E.g., regulated entities shall take action X "in accordance with such regulations as the Secretary may prescribe.")

In recent decades, courts have grown increasingly skeptical of agency deference.

The Supreme Court has chipped away at *Chevron* over time and has not relied on *Chevron* in any of its majority opinions since 2016.

Agency Authority: *Loper Bright Enterprises v. Raimondo* (2/2)

After *Loper Bright*, certain factors may become even more important when courts assess challenges to agency actions.

An agency policy is more likely to be overturned if…	An agency policy is less likely to be overturned if…
▪ The agency "filled a gap" or exercised discretion by: ○ Regulating on an issue that Congress did not address; or ○ Defining detailed requirements based on high-level statutory language	▪ The agency sticks closely to the topics and phrases that Congress used in the underlying law ▪ Congress expressly delegated policymaking authority to the agency
▪ The agency has significantly changed its policy position over time (flip flopping), or announced a new interpretation of an old statute (e.g., to address a new problem that didn't exist when the statute was enacted)	▪ The agency published an interpretation of the statute shortly after it was enacted, and has not altered its position since then

Arbitrary & Capricious Review: *Ohio v. Environmental Protection Agency (EPA)*

Background. An agency action will be struck down as "arbitrary and capricious" if an agency fails to address all important issues raised during the public comment period.

In ***Ohio v. EPA,*** the Court heightened the threshold for what counts as an "important issue" that agencies must respond to point-by-point during public "notice and comment" periods.

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Statute of Limitations: *Corner Post v. Board of Governors of the Federal Reserve System*

Background. Generally, there is a 6-year limit for challenging agency actions (the "statute of limitations"). Historically, this 6-year period was understood to begin on the date of the final agency action (e.g., the publication of a final rule).

In ***Corner Post,*** the Court decided that the 6-year timeline begins running from the date the plaintiff is injured.

Key implication: Even if a rule was issued decades ago, it could be challenged by a newly established company that experiences a new injury.

That challenge will be adjudicated under the modern, less deferential standard of review.

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Implications for Health Care

Overall Implications

Executive Branch

- **Agencies may become increasingly slow, and increasingly cautious** about taking bold actions beyond Congress's express directives or delegations of policymaking.
- **Agencies may have less flexibility to change policies over time**, once a court has decided the single best interpretation.

Note: Agencies were already getting slower and more cautious due to growing judicial skepticism, even before *Loper Bright*

Judicial Branch

- Expect **more frequent litigation, especially to older rules** that were previously protected by 6-year statute of limitations.
- **Agencies may lose more often in lower-profile cases,** where *Chevron* deference was more common. But in higher-profile decisions, courts were already growing more skeptical of agency action.

Note: Standard limits on lawsuits continue to apply, including:

- Plaintiff must have standing to sue,
- Congress can bar judicial review for certain types of actions

Legislative Branch

- **To protect agency actions from judicial challenge,** Congress could…
  - Be more specific in defining agency requirements
  - Expressly delegate policymaking authority to the agency
- These outcomes may be challenging in a polarized environment, particularly on higher-profile issues.

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Implications for Hospital Payments

State Directed Payments (SDPs)

- **Congress has not expressly authorized SDPs in statute.**
  - CMS justifies its SDP regulations based on high-level requirements for CMS oversight of Medicaid spending and rates for managed care organizations (MCOs).
  - This scenario presents potential risk under *Loper Bright* (high-level statute, detailed implementing regulations).
- **It is unlikely that anyone would challenge key aspects of CMS's SDP rules,** such as the overall authority to create SDPs or the cap at the average commercial rate. Those most likely to oppose these policies (e.g., a disgruntled taxpayer concerned about spending) likely do not have standing to sue.
- **However, states or MCOs may have the ability and interest to challenge specific SDP rules.** *Loper Bright* decreases CMS's odds of winning in court. For example:
  - ***Provider attestation requirements*** concerning provider taxes and "hold harmless" agreements. Texas successfully challenged CMS's prior guidance on this point, and has already filed a challenge to CMS's new rule.
  - ***Separate payment terms,*** an SDP financing mechanism that is prohibited as of July 2027.

Disproportionate Share Hospital (DSH) Payments

- **CMS's DSH policies have been repeatedly litigated**, including:
  - CMS's federal regulations on DSH payments under both Medicare and Medicaid
  - CMS approval of state-specific Medicaid DSH methodologies
- **In some prior cases, CMS received Chevron deference**. This suggests that, if litigated after *Loper Bright*, some of those cases may have come out differently.

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Medicaid Program: Other Implications

The Medicaid statutes contain several high-level requirements and competing priorities. It remains to be seen how courts will assess these laws after *Loper Bright*.

Example: FFS payments must be "consistent with efficiency, economy, and quality of care and must also be "sufficient" to attract enough providers.

Areas That May Be More Vulnerable to Legal Challenge After *Loper Bright*	Areas Where *Loper Bright* May Have Less of an Impact
Medicaid Financing. States and CMS have clashed over permissible provider taxes and other policies, including CMS's proposed Medicaid Fiscal Accountability Rule (MFAR). *Loper Bright* may strengthen states' arguments that CMS sometimes goes too far. **Managed Care Networks and Oversight.** Congress has defined high-level standards, which CMS has filled in with detailed regulations on network adequacy, max wait times, rate setting, quality monitoring, etc. High-level statute + detailed regulations = risk under *Loper Bright*.	**1115 Demonstrations** ▪ Demonstrations must "promote the objectives" of the Medicaid program. ▪ Courts have not deferred to CMS in recent waiver disputes (e.g., work requirements), meaning *Chevron* didn't come into play. **Reporting and Audit Requirements** ▪ Congress expressly authorized CMS to define reporting and oversight mechanisms for states. ▪ This may help to explain CMS' reliance on transparency as an oversight tool.

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Implications for Prescription Drug Coverage and Pricing

340B Drug Discount Program

- **Most key 340B program details are defined in statute**. Congress delegated little 340B policymaking authority to the Health Resources and Services Administration (HRSA).
- After *Loper Bright*, **HRSA may be increasingly constrained in trying to regulate around the edges**, including:
  - Manufacturer restrictions on ***contract pharmacies*** (an issue HRSA has already lost on in court).
  - The ***definition of a "patient*** of a 340B covered entity."

Medicaid Drug Rebate Program (MDRP)

- **Some MDRP aspects are clearly defined in statute**, leaving little discretion for CMS (e.g., requirement to cover all FDA-approved drugs, limitations on prior authorization, calculation of rebates).
- **CMS has exercised more discretion in other areas,** potentially creating litigation risk under *Loper Bright.* For example:
  - CMS' pending proposal for a drug price verification survey
  - The definition of a "line extension"

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Implications for Other Health Policies

Lab-Developed Tests (LDTs)

- Under a recent rule, **FDA will increase its oversight of LDTs** (while continuing to exercise enforcement discretion for a small subset of LDTs).
- **This change in policy may create risk under *Loper Bright*.** FDA's new rule reinterprets the statutory definition of "medical device."

Non-Discrimination Policies

- **The non-discrimination protections in Section 1557** have been interpreted differently by different administrations, especially as to whether section 1557 protects against discrimination based on sexual orientation and gender identity (SOGI)
- After *Loper Bright*, courts must determine, once and for all, whether section 1557 includes SOGI protections.

Behavioral Health Parity

- CMS plans to finalize updated requirements for **mental health and substance use parity in commercial health plans**, including enhanced scrutiny of utilization management, provider networks, and provider payment.
- When agencies update existing rules without any statutory change, that may create risk under *Loper Bright*.

Conditions of Participation (CoPs)

- Some **Medicare and Medicaid CoPs** are more clearly defined in statute than others. In some (but not all) areas, Congress has delegated policymaking authority to CMS.
- *Loper Bright* may make CMS more hesitant to define detailed *mandatory* CoPs without express authorization, and could support challenges by providers that certain current CoPs are too prescriptive.

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