HEALTHCARE REGULATORY ROUND-UP EPISODE #79

End of *Chevron* Deference: Opportunities and Threats for the Healthcare Industry

September 25, 2024

Introductions

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Judicial Review of Agency Actions

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Chevron Deference

- Agencies derive authority to make/enforce regulations from statutes
  - E.g., CMS' authority derived from Social Security Act
  - If regulated don't like regulation, file lawsuit challenging agency's authority
- *Chevron*: If statute ambiguous (2 or more reasonable interpretations), court defers to agency interpretation, provided it is *permissible* construction
  - Assume Congress delegated authority to agency to interpret ambiguous statute (vs. requiring agency to follow 'most reasonable' interpretation)
- Since 1984, federal courts applied *Chevron* deference in 18,000+ cases challenging regulations based on ambiguous statute
  - Agency prevailed in ~90% of cases (i.e., court found regulation based on permissible construction of ambiguous statute)
  - Regulated entities more successful when court determines statute is unambiguous

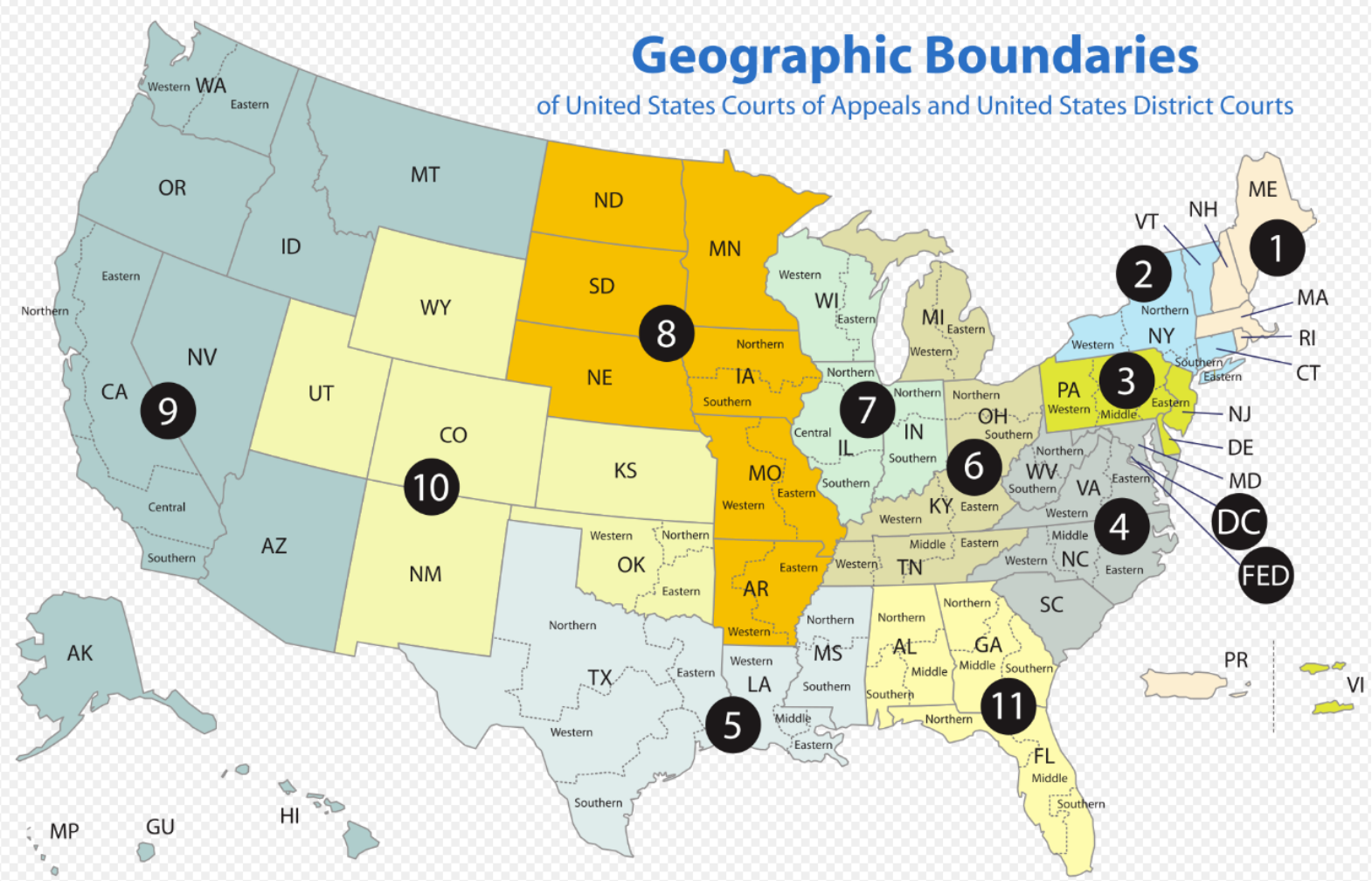
Other Rules of Judicial Deference

- Agency's interpretation of its own regulations (e.g., State Operations Manual)
  - *Kisor* deference – defer to agency's reasonable construction of ambiguous regulatory language unless plainly erroneous, inconsistent with regulation, and/or after-the-fact rationalization
- Other agency actions (e.g., opinion letters, enforcement action)
  - Agency failure to provide notice and comment requires by 42 USC 1395hh (substantive vs. procedure rule)
  - *Skidmore* deference – defer to agency action only if it has 'power to persuade,' e.g., based on long-standing, consistent, and/or contemporaneous interpretations of authorizing statute

End of *Chevron* Deference

- *Loper Bright Enterprises*: Courts, not agencies, are final authority in interpreting statutes
  - "Courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority... Careful attention to the judgment of the Executive Branch may help inform that inquiry. And when a particular statute delegates authority to an agency consistent with constitutional limits, courts must respect the delegation, while ensuring that they agency acts within it. **But courts need not and may not defer to an agency interpretation of the law simply because a statute is ambiguous**."
  - "The statute still has a best meaning, necessarily discernible by a court deploying its full interpretive toolkit."
  - Regulations previously upheld applying *Chevron* deference remain in effect
- *Corner Post*: Statute of limitations on challenges to regulation starts when party suffers injury, not regulation's effective date

Federal Court System



Preliminary Injunction

- Temporary relief to preserve status quo until case decided on merits
  - Motion filed by plaintiff when lawsuit initiated (or soon thereafter)
- Burden of proof
  - Plaintiff will suffer irreparable injury (not compensable through award of monetary damages) in absence of preliminary injunction
  - Threatened injury to plaintiffs party outweighs harm to defendant resulting from injunction
  - Injunction not adverse to public interest
  - Plaintiff demonstrates substantial likelihood of success on merits
- Order of injunctive relief
  - Reasons for issuance (why)
  - Describe in reasonable detail act(s) restrained or required (what)
  - Specify scope of injunctive relief (who, where, when)

Loper Bright's Immediate Impact

Policy Challenges

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Section 1557 Final Rule

- ACA Section 1557 prohibits discrimination based on race, color, national origin, sex, age, or disability in health programs/activities receiving Federal financial assistance
  - Applies to Medicare/Medicaid participating providers, Medicare Advantage plans, Medicare Part D plans, state Medicaid agencies, Medicaid managed care plans, qualified health plans (non-exclusive list)
- HHS Office of Civil Rights published Final Rule in April 2024 to be effective July 5, 2024
  - 2016 Final Rule superseded by 2020 Final Rule which is now superseded by April 2024 Final Rule

Key Provisions

- Defines discrimination *on the basis of sex* to include discrimination based on sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes
- Replaces blanket abortion and religious freedom exemptions with new religious freedom and conscience protections exemptions process
- Extends non-discrimination requirements to telehealth services and patient care decision support tools (artificial intelligence)
  - Make reasonable efforts to identify tools that employ input variables/factors measuring race, color, national origin, sex, age, or disability and make reasonable efforts to mitigate risk of discrimination
- Imposes administrative duties to ensure compliance with anti-discrimination requirements

Recent Court Action Relying on *Loper Bright*

- *Tennessee v. Becerra* (S.D. Miss)
  - Attorneys General in 15 states challenging gender identity provisions
  - July 3 nationwide preliminary injunction of provisions prohibiting discrimination based on gender identity
    - Includes 42 C.F.R. §§ 438.3, 438.206, 440.262, 460.98, and 460.112; 45 C.F.R. §§ 92.5, 92.6, 92.7, 92.8, 92.9, 92.10, 92.101, 92.206-211, 92.301, 92.303, and 92.304 "in so far as these regulations are intended to extend discrimination on the basis of sex to include discrimination on the basis of gender identity."
- *Florida vs. HHS* (M.D. Florida)
  - July 3 Florida-only preliminary injunction of provisions prohibiting discrimination based on gender identity (but shorter list of impacted regulatory provisions)
- *Texas v. Becerra* (E.D. Tex.)
  - July 3 preliminary injunction of all portions of Final Rule "as to Texas and Montana and all covered entities in those States until further order of the Court"
  - Court refused to limit injunction to gender identity provisions

OCR Website

Pursuant to decisions by various district courts regarding the 2024 Final Rule implementing Section 1557, entitled Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37,522 (May 6, 2024) ("2024 Final Rule"), provisions are stayed or enjoined as indicated below:

1. In *Florida v. Department of Health and Human Services*, No. 8:24-cv-1080-WFJ-TGW (M.D. Fla.), the court stayed 45 C.F.R. 92.101(a)(2)(iv), 92.206(b), 92.207(b)(3)-(5), and 42 C.F.R. 438.3(d)(4), in Florida. OCR also may not enforce the interpretation of discrimination "on the basis of sex" in 45 C.F.R. 92.101(a)(2)(iv), 92.206(b), or 92.207(b)(3)-(5) in Florida.

2. In *Tennessee v. Becerra*, No. 1:24cv161-LG-BWR (S.D. Miss.), the court stayed nationwide the following regulations to the extent they "extend discrimination on the basis of sex to include discrimination on the basis of gender identity": 42 C.F.R. 438.3, 438.206, 440.262, 460.98, 460.112; 45 C.F.R. 92.5, 92.6, 92.7, 92.8, 92.9, 92.10, 92.101, 92.206-211, 92.301, 92.303, 92.304; and enjoined HHS from enforcing the 2024 Final Rule "to the extent that the final rule provides that 'sex' discrimination encompasses gender identity."

3. In *Texas v. Becerra*, No. 6:24-cv-211-JDK (E.D. Tex.), the court stayed the 2024 Final Rule in its entirety in Texas and Montana.

https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html

Federal Trade Commission Non-Compete Ban

- FTC published Final Rule in April 2024 to be effective September 4, 2024
  - Entering into or attempting to enforce prohibition on or penalty for work after employment ends constitutes unfair trade practice (with limited exceptions)
- Dueling decisions
  - July 23 decision by federal district court in Pennsylvania upholding FTC's authority to promulgate and enforce non-compete ban
  - August 20 decision by federal district court in Texas enjoining rule's enforcement nationwide based on FTC's lack of authority to promulgate non-compete ban
- FTC website
  - "On August 20, a district court issued an order stopping the FTC from enforcing the rule on September 4. The FTC is considering an appeal. The decision does not prevent the FTC from addressing noncompetes through case-by-case enforcement actions."

More to Come

- State of Texas' challenge to HIPAA Privacy Rule to Support Reproductive Healthcare Privacy (lawsuit filed September 4)
- State of Texas' challenge to Public Health Service Act's requirement to dispense contraception without parental consent (lawsuit filed July 25)
- American Home Care Association's challenge to nursing facility minimum staffing rules (lawsuit filed May 23)
- Texas Medical Association's ongoing challenges to No Surprises Act regulations
- Letters from U.S. House committee chairs to HHS (and other agencies) requiring identification of regulations potentially subject to reversal following *Loper Bright*

Reimbursement Challenges

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Recent Reimbursement Challenges

Definition of “Patient” – 340B Drug Pricing Program

- HRSA = individual's eligibility as 340B patient depends on whether health care service resulting in prescription was initiated by covered entity
- In November 2023, federal district court in South Carolina ruled HRSA’s interpretation contrary to dictionary definition of ‘patient’
- HRSA did not appeal, but its website states ruling is only binding on plaintiff in that case (Genesis Health Care), and HRSA maintains its 1996 Patient Definition Guidelines
  - Litigation seeking broader remedy?

https://www.hrsa.gov/opa/educational-resources/patient-definition-resources

Recent Reimbursement Challenges

Medicare Wage Index - Low-Wage Adjustment

- Statute: wage indexes based on hospital wages surveys in given market
- CMS regulation: upward adjustment for hospitals in lowest quartile applied in budget neutral manner (i.e., reduces payments to other hospitals)
- Multiple hospitals sued CMS based on 2019 redistributions to wage indexes
- In July 2024, federal appeals court ruled CMS lacked authority to redistribute
  - CMS' "task is unambiguous: to calculate a factor that reflects geographic-area wage-level differences, and nothing else"
- CMS response?
  - Appeal to Supreme Court?
  - Litigate remedy in district court, e.g., apply ruling to plaintiff hospitals only?
    - Similar to Rule 340B remedy?
- Congressional action?

Recent Reimbursement Challenges

Medicare Disproportionate Share Payment Calculations

The Formula*: DSH Patient Percent = (Medicare SSI Days / Total Medicare Days) + (Medicaid, Non-Medicare Days / Total Patient Days)*

- Definition of “Medicaid patient” to calculate Medicaid days (Section 1115 waiver days)
- Patients entitled to SSI benefits to calculate Medicare SSI days (entitled to but not receiving)
- Inclusion of Medicare Advantage days to calculate Medicare days (retroactive change)

Coming Soon To a Courtroom Near You…?

- Off-campus HOPD payments (budget neutrality)
- Medicare Advantage (e.g., plan audits, risk adjustment, Star ratings, D-SNAP)
- State challenges to Medicaid rules (e.g., hold harmless, continuous eligibility)
- Hospital qualification for specific status (CAH, SCH, MDH, LVH)
- At-home care reimbursement and wages
- 340B contract pharmacies
- ACA implementation (e.g., fixed indemnity insurance plans, short-term limited duration health plans)
- OIG enforcement authority (e.g., statistical sampling, corporate integrity agreements)

Best Defense May Be a Good Offense

- Identify and challenge underlying basis for government investigation/ enforcement action
  - Regulation vs. agency interpretation of regulation
- Potential chilling effect on enforcement actions?
  - Agencies' confidence in defending challenges to underlying basis for such actions?

Pursuing Legal Action Against CMS

- Identifying and isolating problematic provisions
  - Analyzing data to demonstrate impact on providers
- Evaluating strength of claim against CMS action
  - Determining legislative intent, history of regulations and related guidance
  - Developing detailed position statement
- Identifying and engaging similarly situated providers
  - Winners and losers
  - Sharing litigation expenses (and eventually monetary awards)
- Selecting legal counsel and expert witnesses
- Defining role of state and national associations
- Pursuing administrative remedies (e.g., PRRB)
- Engaging in forum shopping (everything is bigger in Texas….)

“Profound Implications”

- More specific statutory language?
  - Passing legislation often relies on broad and uncomplicated language
- Longer *Federal Register* notices?
- Agency timidity (e.g., regulation of AI, payments for virtual services)?
- Sibling rivalry/tribalism?
- Impact on industry’s financial condition?
  - Court-imposed remedies for unauthorized agency actions?
  - Reduced access to capital due to market uncertainty?
    - Hospital bond disclosure documents now list *Loper Bright* under risk factors

Our Next Healthcare Regulatory Round-Ups

October 9 - Are Your Ducks in a Row? HIPAA Rule Supporting Reproductive Privacy, New Anti-Discrimination Requirements

October 23 – 340B Update

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