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SESSION 3

A New Era for Interacting with Federal Agencies

January 24, 2025

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Housekeeping (*continued*)

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Speaker Introductions

Matt Krueger
Partner

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Matt Krueger is a former U.S. Attorney and partner in the firm's Government Enforcement Defense & Investigations practice. He helps companies and individuals navigate government enforcement and complex litigation challenges, including False Claims Act and white collar matters.

Matt also assists companies in mitigating risk by advising on compliance programs and conducting sensitive internal investigations, working with clients in a range of industries, with a focus on the health care sector, cybersecurity, and data privacy matters.

Matt defends health care and life sciences companies in government investigation and enforcement actions, conducts sensitive internal investigations, and leads high-stakes litigation matters. As a federal prosecutor and in private practice, Matt has handled civil and criminal health care cases on a range of issues and clients, including matters involving the False Claims Act, Stark Law, the Anti-Kickback Statute, the Controlled Substances Act, medical device makers, hospitals and physician groups, pharmacies, skilled nursing facilities, and laboratories.

Speaker Introductions

Martie Ross

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Following a successful two-decade career as a healthcare transactional and regulatory attorney, Martie now serves as a trusted advisor to providers navigating the ever-expanding maze of healthcare regulations. Her deep and wide understanding of new payment and delivery systems and public payer initiatives is an invaluable resource for providers seeking to strategically position their organizations for the future. Martie identifies opportunities and develops realistic plans of action where others only see obstacles.

Martie synthesizes complex regulatory schemes and explains in straightforward and practical terms their impact on providers. She has made hundreds of presentations to professional and community organizations on a broad range of industry topics. Martie provides dynamic, customized educational and planning sessions for directors, executives, and managers, and employee compliance training programs.

Martie received a Bachelor of Arts and a Juris Doctor from the University of Kansas. She is an active member of the American Health Law Association, the Kansas Association of Hospital Attorneys, and the Greater Kansas City Society of Healthcare Attorneys.

Presentation Overview

- Post-*Chevron* World
  - Overview of *Chevron* and *Loper Bright*
  - Regulatory Challenges Post-*Chevron*
- Changes Under Trump Administration
  - Approach to Rulemaking
  - Approach to Administrative Enforcement
  - Approach to False Claims Act Enforcement
- Takeaways for Your Organization

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Post-*Chevron* World

Polling Question #1

Chevron Deference

- Agencies derive authority to make/enforce regulations from statutes:
  - E.g., Centers for Medicare and Medicaid's (CMS) authority derived from Social Security Act
  - If regulated don't like regulation, file lawsuit challenging agency's authority
- *Chevron*: If statute ambiguous (two 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

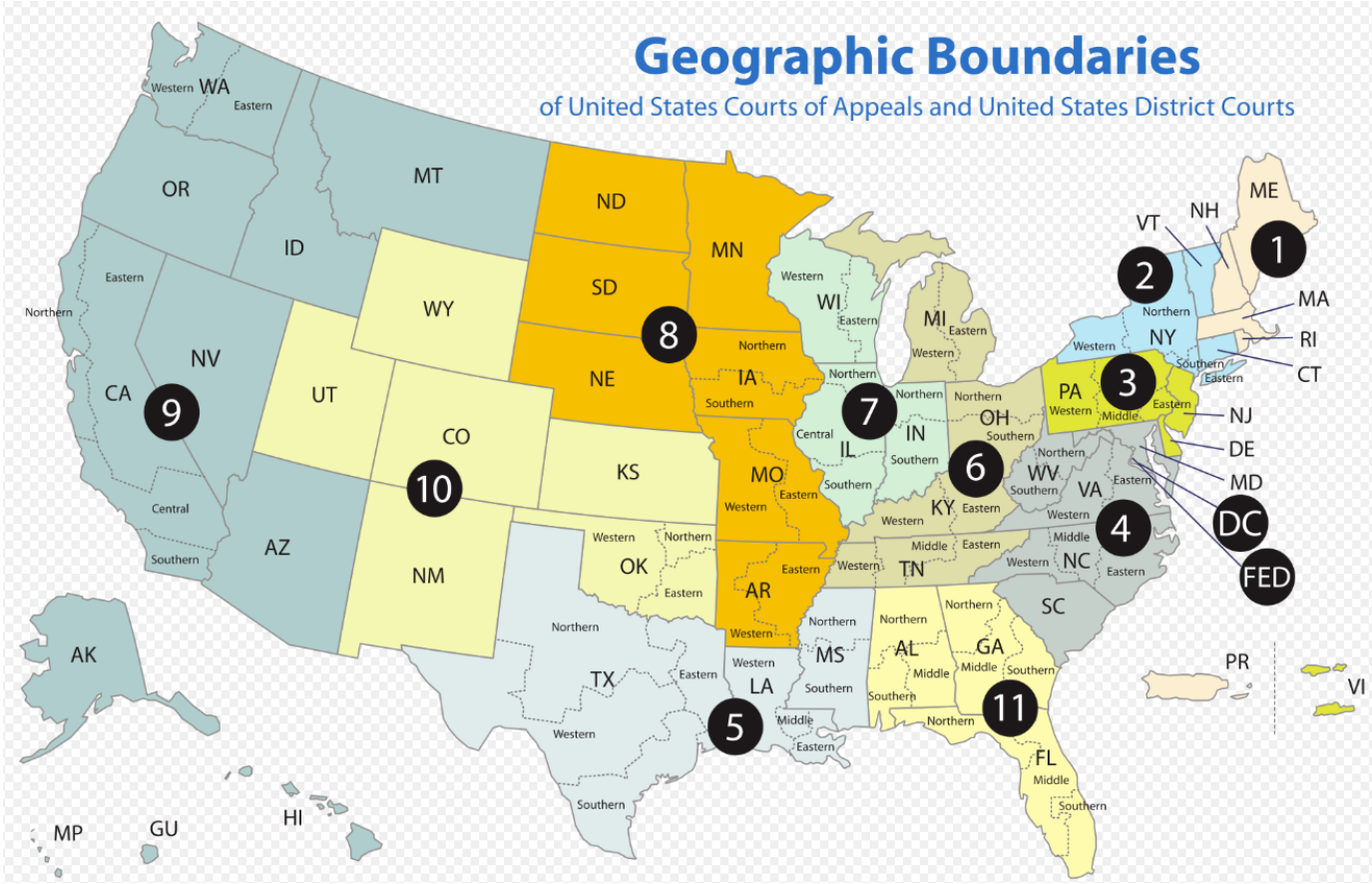
- **Agency's interpretation of its <u>own</u> regulations** (e.g., State Operations Manual)
  - ***Kisor* deference:** Defer to agency's reasonable construction of ambiguous regulatory language unless it is plainly erroneous, inconsistent with regulation, and/or after-the-fact rationalization.

- **<u>Other agency</u> actions** (e.g., opinion letters, enforcement action)
  - Agency failure to provide notice and comment required 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



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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 plaintiff's 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***)

Example – Section 1557 Final Rule

- Section 1557 of the Affordable Care Act (ACA) prohibits discrimination based on race, color, national origin, sex, age, or disability in health programs/activities receiving federal financial assistance.
  - Applies to (*non-exclusive list*):
    - Medicare/Medicaid participating providers
    - Medicare Advantage plans
    - Medicare Part D plans
    - State Medicaid agencies
    - Medicaid managed care plans
    - Qualified health plans

- U.S. Department of Health and Human Services (HHS) Office of Civil Rights (OCR) 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 (AI))
  - 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*."

Recent Court Action Relying on *Loper Bright* (*continued*)

- ***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.

Executive Order (Jan. 20, 2025)

- Titled: “DEFENDING WOMEN FROM GENDER IDEOLOGY EXTREMISM AND RESTORING BIOLOGICAL TRUTH TO THE FEDERAL GOVERNMENT”
  - **Sec. 3(a).** Orders Sec. of HHS to “*provide to the U.S. Government, external partners, and the public clear guidance expanding on the sex-based definitions set forth in this order*.”
  - **Sec. 3(e).** “*Agencies shall remove all statements, policies, regulations, forms, communications, or other internal and external messages that promote or otherwise inculcate gender ideology, and shall cease issuing such statements, policies, regulations, forms, communications or other messages*.”
  - **Takeaway:** Government may change its litigation position in the pending cases.

More to Come

- Texas Assoc. of Home Care & Hospice's challenge to CMS's Special Focus Program
  - Lawsuit filed January 16, 2025
- State of Texas' challenge to HIPAA Privacy Rule to Support Reproductive Healthcare Privacy
  - Lawsuit filed September 4, 2024
  - Preliminary injunction issued in parallel case, Dec. 22, 2024.
- American Home Care Association's challenge to nursing facility minimum staffing rules
  - Lawsuit filed May 23, 2024
- Texas Medical Association's ongoing challenges to No Surprises Act regulations

Coming Soon To a Courtroom Near You…?

- Off-campus Hospital Outpatient Department (HOPD) payments (budget neutrality)
- Medicare Advantage (e.g., plan audits, risk adjustment, Star ratings, Disaster Supplemental Nutrition Assistance Program (D-SNAP))
- State challenges to Medicaid rules (e.g., hold harmless, continuous eligibility)
- Hospital qualification for specific status (Critical Access Hospital (CAH), Sole Community Hospital (SCH), Medicare Dependent Hospital (MDH), or Low-Volume Hospital (LVH)).
- At-home care reimbursement and wages
- 340B contract pharmacies
- ACA implementation (e.g., fixed indemnity insurance plans, short-term limited duration health plans)
- Office of the Inspector General (OIG) enforcement authority (e.g., statistical sampling, corporate integrity agreements)

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Changes Under Trump Administration

What Happens to Biden Administration Rules?

- Executive Order – Regulatory Freeze Pending Review
  - Cannot propose or issue rule until designated department or agency head approves rule
    - OMB Director may exempt rules in 'urgent circumstances'
  - Withdraw rules sent to Office of Federal Register but not yet published in *Federal Register*
  - Postpone for 60 days effective date of rules published in *Federal Register*
- Congressional Review Act
  - Senator or Representative can introduce CRA resolutions to rescind regulations with effective date after 8/1/2024
    - Beginning 1/23/2025 for Senators, 2/5/2025 for Representatives
    - Approximately 100 regulations at risk, including CFPB's medical debt rule
- Roll back regulations now in effect through notice and comment rulemaking
  - Likely targets: nursing home staffing levels, HIPAA reproductive rights, Section 1554
- Exercise enforcement discretion
- Stop, delay, or withdraw proposed rules
  - Proposed changes to HIPAA Security Rule (comments due March 7)?
  - Medicare Advantage/Part D Proposed Rule (comments due January 27), Advance Notice (comments due February 10)

What Happens to Biden Administration Rules? (*continued*)

- Amend or repeal guidance documents.
  - Generally does not require notice and comment rulemaking.
- Stop, delay, or withdraw proposed rules.
  - Issue moratorium on rules under development.
  - Medicare Advantage/Part D proposed rule?
- Exercise enforcement discretion.

Different Approach to Rulemaking and Subregulatory Guidance

- Trump has pledged to rescind regulations, but this raises questions:
  - Rescission of regulations requires notice-and-comment, just like issuing new regulations.
  - Administrative Procedure Act (APA) challenges can be brought to challenge rescission.
- First Trump Administration placed limits on subregulatory guidance:
  - Limited use of subregulatory guidance to impose substantive rules.
  - Required cataloguing of all subregulatory guidance.
  - Restricted use of subregulatory guidance for enforcement matters.
  - E.O. 13891 (Oct. 2019) Promoting the Rule of Law Through Improved Agency Guidance Documents.
- **Takeaway:** Expect slower rulemaking, fewer agency guidance documents.

“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.

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)

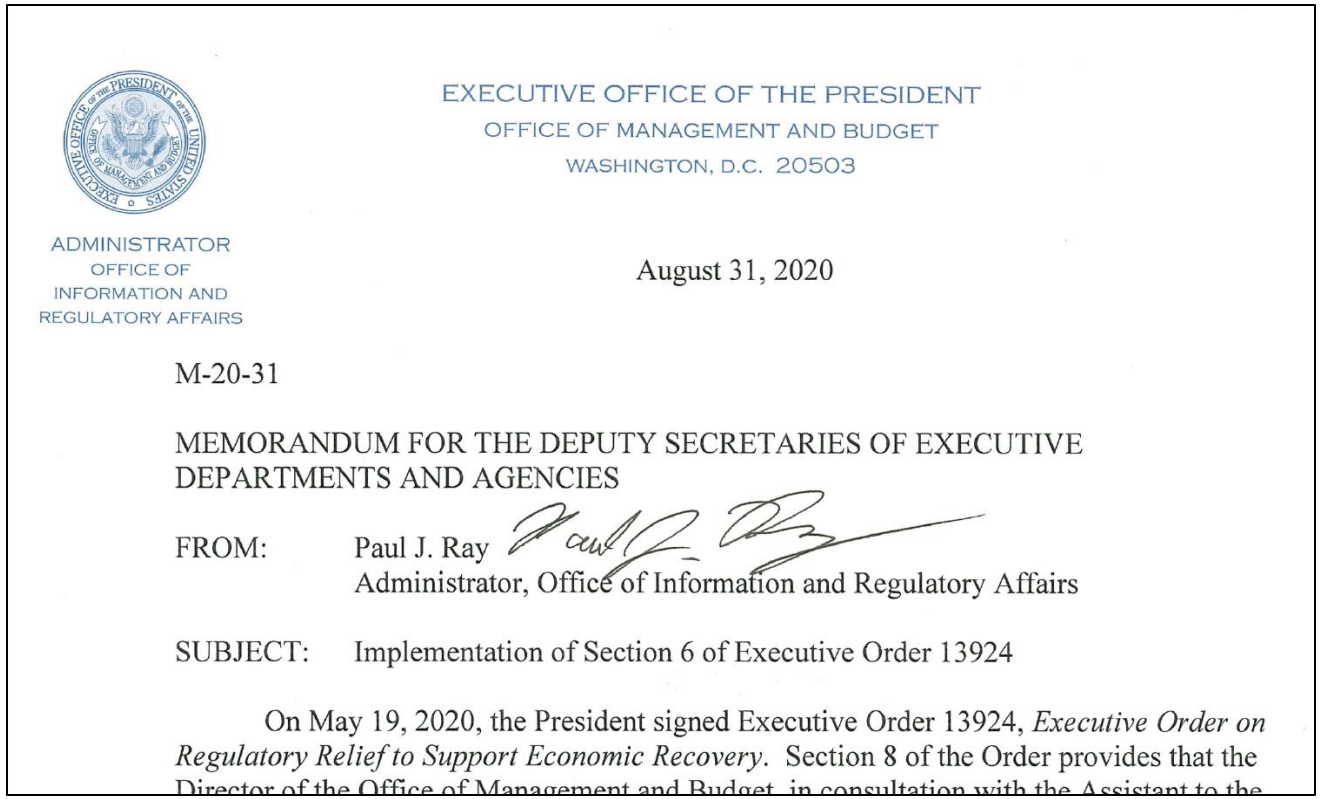
Pursuing Legal Action Against CMS (*continued*)

- Selecting legal counsel and expert witnesses
- Defining role of state and national associations
- Pursuing administrative remedies:
  - e.g., Provider Reimbursement Review Board (PRRB)
- Engaging in forum shopping:
  - Everything is bigger in Texas….

Polling Question #2

Different Approach to Agency Enforcement

- First Trump Administration set out rules for administrative enforcement:
  - Placed burden of proof on agency
  - Agency must disclose any evidence favorable to defendants
  - Fair notice of enforcement basis and procedures
  - OMB, M-20-31 (Aug. 31, 2020)
- We expect similar focus on reforming agency enforcement.



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

August 31, 2020

M-20-31

MEMORANDUM FOR THE DEPUTY SECRETARIES OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM: Paul J. Ray
Administrator, Office of Information and Regulatory Affairs

SUBJECT: Implementation of Section 6 of Executive Order 13924

On May 19, 2020, the President signed Executive Order 13924, *Executive Order on Regulatory Relief to Support Economic Recovery*. Section 8 of the Order provides that the Director of the Office of Management and Budget, in consultation with the Assistant to the

False Claims Act (FCA) Enforcement

- Constitutionality of whistleblower suits under qui tam provisions is being litigated in *U.S. ex rel. Zafirov v. Fla. Medical Assoc.* (11th Circuit).
- DOJ's defense rests upon its claim to closely supervise qui tam litigation. May create opportunity to press for more dismissals by DOJ of qui tam suits.
- *Loper Bright* and Trump Administration's focus on more reforming administrative enforcement creates opportunities to argue that regulations or subregulatory guidance underlying FCA suits are not valid.
- **<u>Takeaway</u>:** Look for defenses based on text of underlying statute and argue that regulations or subregulatory guidance based on statutes are not valid bases for FCA enforcement.

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?

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Takeaways for Your Organization

Polling Question #3

Internal Risk Management

- Evaluating proposed course of action for regulatory compliance frequently involves “predicting” how agency will interpret/apply its rules.
- Determining degree of risk dependent on likelihood agency will adopt unfavorable interpretation.
- Recalibrate risk assessment in light of *Loper Bright*, new administration?

Questions?

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About PYA

For over 40 years, PYA has helped guide healthcare organizations through complex regulatory compliance challenges. PYA offers a comprehensive range of services—designing and evaluating compliance programs, conducting risk assessments, serving as an Independent Review Organization, supporting providers facing investigations or payer audits, advising on reimbursement and revenue management, providing fair market value compensation opinions, and analyzing impacts from acquisitions and affiliations. A nationally recognized healthcare management consulting and accounting firm, PYA serves clients in all 50 states from offices in six cities. PYA consistently ranks among *Modern Healthcare's* Top 20 healthcare consulting firms and *INSIDE Public Accounting's* "Top 100" Largest Accounting Firms.

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