

A (Loper) Bright Future? How the Demise of Chevron Deference Will Affect the Health Care Industry

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I. RIP Chevron – Loper Bright Enterprises v. Raimondo

a. The Chevron Two-Step

i. Before *Loper*, the *Chevron* two-step test was central for determining whether an agency is acting within its statutory authority. See *Chevron USA Inc. v. Natural Resources Defense Council, Inc.*, 467 US 837 (1984).

1. Step 1: Determine “whether Congress has directly spoken to the precise question at issue.” *Id.* at 842-843.

a. Does the statute have a clear, unambiguous meaning? *Id.*

b. “If the intent of Congress is clear, that is the end of the matter.” *Id.*

c. If the statute was “silent or ambiguous” proceed to Step 2. *Id.* at 843.

2. Step 2: Is “the agency’s [interpretation] based on a permissible [or reasonable] construction of the statute[?]”

a. If yes, then defer to the agency’s interpretation Even if not the reading the court would have reached on its own.

b. However, the agency still generally needed to demonstrate that its decision making was not arbitrary. See *id.* at 865 (The Court based its deference in part on the agencies’ ability to weigh competing interests in technical and complex matters “in a detail and reasoned fashion[.]”)).

b. Chevron’s Dissymmetry

1. *Chevron* set a low bar for agencies to defend their regulations.

a. 70% of *Chevron* cases advanced to Step 2.

b. ~94% of Step 2 cases were decided in favor of agencies.

c. Deference led to aggressive agency interpretations.

2. Some commentators have gone so far as to argue that *Chevron* did so much to empower agencies that “[i]t [had] become a kind of *Marbury*, or counter-*Marbury* for the administrative state.” Cass R. Sunstein, *Law*

and Administration after Chevron, 90 COLUM. L. REV. 2071, 2074-75 (1990).

c. *Loper Bright Enterprises v. Raimondo* 144 S. Ct. 2244 (2024)

i. Background

1. Deals with the Magnuson-Stevens Act that governs fishery management in federal waters and provides that the National Marine Fisheries Service may require vessels to carry federal observers onboard to enforce the agency's regulations and pay their salaries.

ii. Issue

1. "Does a statutory silence or ambiguity then go to a court for resolution? Or to an agency?"

iii. Lower Court (Relying on *Chevron*)

1. The statute is not "wholly unambiguous," and the agency's interpretation was reasonable. *See Loper*, 144 S. Ct. at 2256.
2. "Because there remained 'some question' as to Congress's intent. . . the court proceeded to *Chevron's* second step and deferred to the agency's interpretation as a 'reasonable' construction of the MSA[.]" *Loper Bright*, 144 S.Ct. at 2256 (internal citations omitted).

iv. Holding, Justice John Roberts (June 28, 2024)

1. *Chevron* deference violates the Administrative Procedure Act (APA)

- a. APA says courts must "decide all relevant questions of law" in cases challenging agency action. *Loper Bright*, 144 S.Ct. at 2265 (quoting 5 U.S.C. § 706).

- i. APA says courts must exercise "independent judgment" in deciding whether an agency has acted within its statutory authority. *Loper Bright*, 144 S.Ct. at 2273.

- b. Courts must use every tool at their disposal to determine the "best reading" of the statute. *Loper Bright*, 144 S.Ct. at 2264.

- i. "[T]he reading the court would have reached' if no agency were involved[.]" *Loper Bright*, 144 S.Ct. at 2266.

- ii. "Statutory ambiguity...is not a reliable indicator of actual delegation of discretionary authority[.]" *Loper Bright*, 144 S.Ct. at 2272.

d. *Loper* Limitations

- i. The "informed judgment" of an agency is still be entitled to "great weight" if persuasive and based on agency expertise. *See Loper Bright*, 144 S.Ct. at 2248-2249 (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944)).

- ii. Only applies in cases concerning whether an agency is properly interpreting *statutory* language.
 - 1. This means that it doesn't apply in disputes re an agency's interpretation of its own regulation. Those disputes are governed by something called *Auer* deference. *See Auer v. Robbins*, 519 US 452 (1997).
 - a. The Supreme Court reaffirmed *Auer* deference in the case *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019).
 - b. However, *Kisor* weakened *Auer* deference by nonetheless requiring judges to ensure that regulations are "truly ambiguous" after "engag[ing] in appropriately rigorous scrutiny of an agency's interpretation of a regulation[.]" *Kisor* 139 S. Ct. 2at 2249
 - c. *Auer/Kisor* doesn't apply in instances in disputes re the reasonableness of an agency's policies when the statute is entirely silent."
- iii. Cannot get around provisions precluding judicial review.
 - 1. Though there is generally a presumption of judicial review, judicial review can still be limited by statute. *See Block v. Community Nutrition Institute*, 467 U.S. 340 (1984) (Despite "the general presumption favoring judicial review. . . [t]hat presumption does not control in cases such as this one. . . since the congressional intent to preclude judicial review is 'fairly discernible' in the detail of the legislative scheme.")
- iv. Holdings that relied on *Chevron* framework still have precedential value:
 - 1. "[W]e do not call into question prior cases that relied on the *Chevron* framework." 144 S. Ct. 2244, 2273
 - a. This means that the 18,000 lower court cases that were decided based on *Chevron* deference remain in effect. *See* Michael Blumenthal et al, *The End of Chevron Deference: What Does It Mean, and What Comes Next?*, AMERICANBAR.ORG, (Aug. 2024), https://www.americanbar.org/groups/business_law/resources/business-law-today/2024-august/end-chevron-deference-what-does-it-mean-what-comes-next/.
- v. Only applies in the context of implicit (not explicit) delegations
 - 1. "Some statutes 'expressly delegate[]' to an agency the authority to give meaning to a particular statutory term" or "empower an agency to prescribe rules to 'fill up the details' of a statutory scheme ..." by using terms "such as 'appropriate' or 'reasonable.'" *Loper* 144 S. Ct. at 2263.

2. In those instances, “the role of the reviewing court [is to] ... effectuate the will of Congress subject to constitutional limits.” *Loper* 144 S. Ct. at 2263.
3. It’s possible that the Supreme Court will turn its attention to more robust enforcement of the non-delegation doctrine, which prohibits Congress from writing statutes that are so vague it’s essentially delegating its law making authority to the executive branch’s agency.

II. How *Loper* is Already Affecting Healthcare Litigation

a. *Lake Region v. Becerra*, 113 F.4th 1002 (D.C. Cir. 2024)

i. Issue

1. Whether CMS’s use of the so-called “fixed-total” method for calculating hospitals volume decrease adjustment (VDA) payments was lawful under the Medicare statute.

ii. Background

1. Medicare statute requires CMS to “fully compensate” Sole Community Hospitals (“SCHs”) and Medicare Dependent Hospitals (“MDHs”) for their “fixed costs” if they experience a 5% decline in discharges. *See* 42 U.S.C. § 1395ww(d)(5)(D)(ii) and 1395ww(d)(5)(G)(iii).
2. Hospitals challenged CMS’s VDA method of comparing their total Diagnosis Related Group (“DRG”) payments (payments for both fixed and variable costs) to just their fixed costs.
 - a. Specifically, plaintiff hospitals argued that “[b]y attributing [DRG] payments solely to fixed costs, the fixed-total method overstates the amount of a hospital’s reimbursed fixed costs and thus understates the amount of [plaintiffs’] unreimbursed fixed costs, shortchanging the hospitals.” *Lake Region*, 113 F.4th at 1006.
3. CMS later reversed course and agreed to compare a hospital’s fixed costs to the portion of its DRG estimated to be for fixed costs. *See e.g. Bon Secours Rappahannock General Hospital v. Palmetto GBA*, Case No. 18-0946, Decision No. 2025-D26, at 2 (May 28, 2025) (“The Board remands the appeal to the Medicare Contractor to recalculate the Provider’s VDA consistent with *Lake Region Healthcare Corp. v. Becerra*.”).
4. However, CMS refused to apply that methodology retroactively, and argued that its old methodology was still “reasonable.”

iii. District Court (before *Loper*)

1. Multiple prior courts, including the Eighth Circuit had previously sided with the government on this issue and, relying heavily on *Chevron*

deference, the D.C. district court followed suit. *See Lake Region*, 113 F.4th at 1007 (citing, e.g., [*Unity HealthCare v. Azar*, 918 F.3d 571, 577-78 \(8th Cir. 2019\)](#); *Stephens Cnty. Hosp. v. Becerra*, No. 19-cv-3020, 2021 WL 4502068, *9-10 (D.D.C. Sept. 30, 2021)).

2. The District Court acknowledged that the plaintiffs' preferred "interpretation might be better than the Secretary's, and the Secretary might have even conceded this point by prospectively adopting that method in 2017[.]" but nonetheless deferred to the agency's interpretation under *Chevron's* because it was nonetheless "a reasonable agency interpretation of an ambiguous statute[.]" *Lake Region Healthcare Corp. v. Becerra*, Civil Action No. 1:20-cv-03452 (JMC) (D.C. Dis. 2022).

iv. Circuit Court Holding (after *Loper*)

1. "*Chevron* has now been overruled, so we must 'exercise independent judgment' in construing the Medicare statute." *See Lake Region*, 113 F.4th at 1007.
2. CMS does not have the best reading of the statute:
 - a. "We hold that HHS's fixed-total approach does not afford the requisite full compensation for fixed costs." *Lake Region*, 113 F.4th at 1007.
 - b. "DRG payments thus unambiguously compensate for *variable* as well as fixed costs. By attributing the payments solely to fixed costs, the fixed-total method overstates the amount of a hospital's *reimbursed* fixed costs and thus understates the amount of its *unreimbursed* fixed costs, shortchanging the hospitals." *Lake Region*, 113 F.4th at 1007.
- 3.

b. *Avon Nursing & Rehab. v. Becerra*, 119 F.4th 286 (2d Cir. 2024).

i. Issue

1. Whether an investigation of a skilled nursing facility was lawful when a registered nurse was not part of the investigation team.

ii. Background

1. The Medicaid statute requires that there be a registered nurse on the teams that perform annual recertification surveys on SNFs. *See* 42 U.S.C. § 1396r(g) ("Surveys under this subsection shall be conducted by a multidisciplinary team of professionals (including a registered professional nurse.")
2. The requirement applies to "*surveys*," but not necessarily to complaint *investigations*.

- a. In contrast to a survey, conducted under 42 U.S.C. § 1396r(g)(2), a complaint investigation is conducted under 42 U.S.C. § 1396r(g)(4).
3. Avon, a SNF, was subject to civil monetary penalties following a complaint investigation where a registered nurse was not part of the team.
4. Part of Avon’s argument turned on the terminology of HHS’s regulations, that refer to these types of inspections not as “investigations” but as “complaint surveys.” *See Avon Nursing*, 119 F.4th at 292 (*citing* 42 C.F.R. § 488.30 and 42 C.F.R. § 488.301).
- iii. Second Circuit rejected Avon’s argument relying heavily on *Loper*:
 1. “[I]n light of *Loper* . . . our interpretation of the statute should not rest on the taxonomy developed by the agency. The registered nurse requirement only extends to *surveys as that term is used in the statute*, regardless of the terminology used by the agency.” *Avon Nursing*, 119 F.4th at 292.
 2. “Allowing the agency’s terminology to control our interpretation of the statute would be an abdication of our duty to interpret the statute independently.” *Avon Nursing*, 119 F.4th at 292.
- c. ***Baptist Healthcare of Oklahoma, LLC v. Becerra*, Case No. [1:2023cv00625](#) (DDC - Pending).**
 - i. Issue
 1. Is CMS interpretation of “hospital’s patient days” to only include patients in areas of a hospital providing services generally payable under IPPS a valid interpretation of the DSH statute?
 2. Specifically, was the PRRB was correct to exclude child and adolescent psychiatric patient days as Medicaid eligible days in the Medicare DSH calculation?
 - ii. Background
 1. This presents a question of statutory interpretation of a “hospital’s patient days.” 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II).
 - a. Issue has been fully briefed before *Loper* was issued, and the agency defended its interpretation of the statute merely as a “permissible construction” of it under *Chevron* Step 2. *See Baptist Healthcare of Oklahoma, LLC v. Becerra*, Case No. [1:2023cv00625](#), ECF No. 17 at 25 (July 14, 2023).
 - b. In July of 2024, the court ordered the parties to re-brief this issue due to how much *Loper* affected the parties’ arguments: “Given this seismic change in the law,” the parties must re-brief the case because, under *Loper*, it “makes no sense to speak of a

‘permissible’ interpretation In the business of statutory interpretation, if it is not the best, it is not permissible.”

iii. During re-briefing, both parties altered each of their arguments to orient the language and reasoning with *Loper*:

1. Hospitals emphasized plain meaning:

a. “[T]he [Medicare] statute requires the DSH payment calculation to include the ‘hospital’s patient days,’ and neither the statutory text nor its purpose leaves room to exclude the patient days in this case[.]” *Baptist Healthcare*, Case No. [1:2023cv00625](#), ECF No. 24-1 at 8 (Oct. 4, 2024).

2. HHS, instead, focused on spirit and context:

a. HHS argued that the plain meaning was not readily apparent in the statute (“The Supreme Court observed recently that “[t]he ordinary meaning of the fraction descriptions, as is obvious to any ordinary reader, does not exactly leap off the page.” *Baptist Healthcare*, Case No. [1:2023cv00625](#), ECF No. 25-1 at 27 (Nov. 8, 2024). (quoting *Becerra v. Empire Health Found.*, 597 U.S. 424, 434 (2022))).

b. HHS argued that the plaintiffs’ interpretation was impractical, that limiting patient days to only those days attributable to units or wards providing acute services “generally payable under the [IPPS]” excludes child and adolescent psychiatric patient days because psychiatric hospitals are excluded from the IPPS. *See Baptist Healthcare*, Case No. [1:2023cv00625](#), ECF No. 25-1 at 10.

c. The agency analogized *Health Alliance*, a *Chevron*-era case where the term “bed days” was not defined in the DSH statute but was found to exclude outpatient observation services. *See Baptist Healthcare*, Case No. [1:2023cv00625](#), ECF No. 25-1 at 30 (citing *Health All. Hosps., Inc. v. Burwell*, 130 F. Supp. 3d 277, 286 (D.D.C. 2015)).

d. The parties’ arguments raise the question of how much *Chevron*-era cases like *Health Alliance*, that may not necessarily turn on *Chevron*, will have precedential or persuasive effect, as notable the Supreme Court in *Loper* indicated that they were not calling “into question prior cases that relied on the *Chevron* framework.” *Loper* 144 S. Ct. at 2273.

d. *Gottlieb Memorial Hospital et al. v. Becerra*, 1:24CV00116 (D.D.C. 2025)

i. Issue

1. Should labor & delivery beds be excluded from the intern-to-bed ratio (IBR) used to calculate indirect medical education (IME) payments?

ii. Background

1. IME payment is driven in part by the IBR. The higher the IBR, the greater the hospital's IME payment will be. A lower bed count would produce a higher IBR, and greater IME payment.
2. Under current IME regulations, labor and delivery beds are included in the bed count that serves as the denominator of the IBR.
3. Labor and delivery beds include any bed that provides labor and delivery services, even if it is not a licensed inpatient bed.
4. CMS rationale: all beds dedicated to services that are payable under IPPS should be included in the IME bed count. Labor and delivery services are covered under IPPS.

iii. Dueling Provisions of the IME Statute

1. Provision 1: IME payment shall be "computed in the same manner as" it was "under regulations (in effect as of January 1, 1983) . . . except as follows."
 - a. This provision was part of the original IPPS statute.
 - b. Prior to IPPS, HHS made IME payments to hospitals as part of the cost limit calculation. Payment was derived in part from each hospital's bed count.
 - c. As of January 1, 1983, labor and delivery beds were excluded from the IME payment calculation, as reflected in contemporaneous manual guidance.
2. Provision 2: The IBR for the current year "may not exceed the ratio of the number of interns and residents...with respect to the hospital for its most recent cost reporting period to the hospital's available beds (as defined by the Secretary) during that cost reporting period."
 - a. This provision was adopted in the Balanced Budget Act of 1997.
 - b. It is known as the IBR cap.

iv. Arguments

1. Plaintiffs' arguments
 - a. The plaintiff hospitals contend that the best reading of the statute requires excluding labor and delivery days from the IME bed count.
 - b. They argue that Provision 1 requires HHS to calculate IME as it was calculated January 1, 1983.
 - i. Labor and delivery beds were excluded from the calculation at that time.

- c. The plaintiffs also contend that adding labor and delivery beds to the IBR is tantamount to changing the statutory IME payment formula.
 - i. The exponent in the IME calculation ($IBR^{0.405}$) reflects the relationship between the IBR and costs, as determined by the Congressional Budget Office in the 1980s.
 - ii. The CBO did not include labor and delivery beds in that calculation.
 - d. The plaintiffs also argue that Provision 2 does not give HHS authority to redefine “beds.”
 - i. Rather, it allows HHS to determine when a bed is deemed to be “available.”
 - ii. And only for purposes of determining the IBR cap—not the IBR itself.
2. HHS’s arguments
- a. HHS argues that the best reading of the statute is that Congress expressly gave the agency discretion to define beds.
 - i. HHS argues that Provision 2 expressly gives HHS authority to define beds.
 - ii. Therefore, the question is whether HHS’s definition is arbitrary and capricious—not whether it contradicts the statute.
 - b. HHS argues that Provision 1 only requires IME payment in accordance with “regulations” in effect as of January 1, 1983.
 - i. The contemporary manual guidance that excluded labor and delivery beds was allegedly not a “regulation” within the meaning of Provision 1. Per HHS, “[I]t is black letter law that manual provisions are not ‘regulations.’”

III. How Might *Loper Bright* Affect Ongoing Litigation (28)

a. The Protest Requirement

- i. Hospitals filed a complaint on June 28, 2022, challenging CMS’s policy that hospitals must “protest” all issues they intend to appeal to the PRRB in their cost reports. *See Froedtert Memorial Lutheran Hospital v. Becerra*, Case No. 22-cv-2237 TJK (D.D.C.) (*Pending*).
 - 1. Plaintiffs basing their argument in part on *Bethesda Hospital Association v. Bowen*, 485 U.S. 399, 404 (1988) (“No statute or regulation expressly mandates that a challenge to the validity of a regulation be submitted first to the fiscal intermediary.”)

2. Far reaching implications for hospitals – potentially leading to CMS refusing to pay hospitals even when hospitals win on appeal.
- ii. HHS rationale: Statute authorizes HHS to withhold payment if hospitals fail to present all information necessary “to determine amount due to [a] provider”
 1. Is HHS’s interpretation the “best reading” of the statute?
 - a. Deprives PRRB of power to adjust items not considered by the MAC.
 - b. Deprives PRRB and Courts of the power to compel payment.

b. Ongoing Standardized Amount Litigation

- i. Hospitals are filing appeals alleging that the present-day IPPS payment rates are understated due to errors made back in the 1980s.
- ii. Alleged error #1 – Inclusion of transfer cases in the inaugural standardized amount calculation, a.k.a. the “transfers v. discharges” issue.
 1. The Medicare statute gave HHS specific instructions for calculating the standardized amount for the first year of IPPS (1984).
 2. The first step in the process was to determine total allowable costs and total discharges from a base year. The statute directed HHS to divide the total allowable costs from the base year by the discharges from that same year. The result of that calculation (the average cost per discharge) was to form the basis of the standardized amount.
 3. HHS used 1981 as the base year. The 1981 cost report data did not distinguish between transfers and discharges. A transfer refers to a case where a patient is moved from one hospital to another. It is distinct from a discharge.
 4. HHS included transfer cases in the denominator of the average cost per discharge. This had the result of diluting the average cost per discharge, thereby understating the inaugural standardized amount.
 5. HHS acknowledged its error in 1991 when it established the capital PPS. To avoid the same error in the capital PPS rates, HHS applied a “correction factor” of 0.9911 to remove the effect of transfer cases in the capital PPS standardized amount.
 6. The estimated impact of this issue is approximately 1% on IPPS payments.
- iii. Alleged error #2 – The continuation of the 1985 budget neutrality adjustment, a.k.a. the 1985 budget neutrality issue.
 1. Congress instructed HHS to adjust the standardized amount in the first two years of IPPS to ensure that aggregate IPPS payments in those years were no more or less than what Medicare would have paid under the reasonable cost system.

2. These were intended to be temporary adjustments. The statute gave express instructions for how to calculate the rates after 1985 and those instructions indicated that the budget neutrality adjustment should be removed.
 3. In FY 1985, HHS estimated that IPPS would be about 6% more expensive than reasonable cost that year and therefore applied a budget neutrality adjustment to the rates of about 6%.
 4. In FY 1986, HHS decided that the statute did not unambiguously require it to remove the FY 1985 budget neutrality adjustment. Therefore, the agency advanced the near 6% adjustment into FY 1986. That adjustment remains in the rates to this day.
- iv. *St. Mary's Regional Medical Center v. Becerra*, Case No. 1:23-cv-1594-RCL (D.D.C. Dec. 20, 2024) (Challenging Error #1)

1. Procedural Background

- a. Hospitals filed appeals with the PRRB challenging the inclusion of transfer cases in the inaugural standardized amount.
- b. The PRRB initially determined that these appeals are barred by the so-called “predicate facts” rule, which prevents Medicare contractors from revisiting factual determinations made over three years ago. The D.C. Circuit reversed the PRRB on appeal, holding that the predicate facts rule only applies to reopenings, and does not bar appeals challenging facts determined more than three years ago. *Saint Francis Med. Ctr. v. Azar*, 894 F.3d 290 (D.C. Cir. 2018).
- c. Following the D.C. Circuit’s decision in *Saint Francis*, the PRRB again dismissed transfers v. discharges appeals, but on different grounds.
 - i. Zero impact – The Board determined that any errors HHS made in FY 1984 are immaterial because today’s rates are derived from the budget-neutralized standardized amount from FY 1985. Had HHS calculated a larger inaugural standardized amount in FY 1984, the agency would have applied an even bigger adjustment to the FY 1985 rates to budget neutralize them to the reasonable cost system.
 1. “Providers would not be able to flow forward any adjustments made to the FFY 1984 standardized amounts because: (1) they, again, would not be able to get through the FFY 1984 and 1985 budget neutrality adjustments that Congress

otherwise fixed to an external point (no greater and no less); and (2) the IPPS rates paid for FFYs 1984 and 1985 are based on standardized amounts that were adjusted downwards as a result of the budget neutrality adjustment for FFY 1984 and also for FFY 1985.”

- ii. Precluded from review – The PRRB ruled that any challenge to the inaugural standardized amount is “inextricably tied” to the 1985 budget neutrality adjustment, which is itself precluded from review.

- 1. “There shall be no administrative or judicial review...of...the determination of the requirement or the proportional amount, of any adjustment effected pursuant to” Congress’ mandate to budget neutralize the IPPS rates in FYs 1984 and 1985. 42 U.S.C. § 1395ww(d)(7)(A).

- d. Hospitals appealed the PRRB’s decision to D.C. District Court.

2. Holding, Judge Royce Lamberth (Dec. 20, 2024)

- a. HHS erred in carrying forward the 1985 budget neutrality adjustment into FY 1986 (i.e., Error #2). “The statute simply supplies no basis for carrying forward the budget-neutralized standardized amounts from 1985 to 1986; to the contrary, it forbade the Secretary from doing so.”
- b. HHS cannot use Error #2 to shield itself from liability for Error #1. “The Secretary cannot use his error of 1986 to launder the effects of his alleged error in 1983.”
- c. The provision barring review of the 1985 budget neutrality adjustments does not also bar review of alleged errors in the inaugural standardized amount. “The Secretary may not flout Congress’ chosen methodology, argue sophistically that he did so in the name of budget neutrality, and then claim the aegis of the Preclusion Provisions to shield his error from review.”
- d. A challenge to Error #1 is not “unavoidably a challenge” to the budget neutrality adjustments shielded from review.

3. Government’s motion to clarify (Jan. 17, 2025)

- a. HHS filed a motion for the court to clarify its December 20, 2024, decision. HHS argues that the court should have limited

its decision to addressing the PRRB's decision dismissing the appeals for lack of jurisdiction. HHS argues the court went too far in addressing Error #2 because the agency was allegedly not on notice to brief that issue.

b. Plaintiffs: The government's "apparent remorse over how [it]" addressed Error #2 in its briefs "does not warrant a mulligan in this court."

c. The motion is fully briefed.

v. Implications of *St. Mary's* for Error #2

1. The *St. Mary's* Court ruled that it was unlawful for HHS to carry forward the 1985 budget neutrality adjustment. Error #2 was indeed an error.
2. But the plaintiffs were not seeking relief for Error #2. The Court simply found that HHS cannot use Error #2 to shield itself from liability for Error #1.
3. This means that if the *St. Mary's* plaintiffs ultimately prevail on appeal, they will only be entitled to relief for Error #1. "If their challenge should succeed, the Secretary would be required to calculate what the plaintiffs' 2019 compensation would have been if the Secretary had excluded transfers from the inaugural cost-per-discharge calculation."
4. The PRRB itself has ruled that Errors #1 and #2 are distinct issues that must be appealed separately. The PRRB has issued a slew of decisions dismissing perceived attempts to insert Error #2 into appeals originally filed for Error #1.
5. On February 28, 2025, hospitals filed a complaint in D.C. District Court challenging Error #2. The case is captioned *University of Kansas Hospital Authority v. Kennedy*.

c. **FTC's Non-Compete Rule**

i. *Ryan LLC, v. F.T.C.*, Civil Action No. 3:24-CV-00986-E (N.D. Tex. 2024)

1. Issue

- a. Does the "FTC's ability to promulgate rules concerning unfair methods of competition include the authority to create substantive rules regarding unfair methods of competition[?]"

2. Background

- a. FTC promulgated the "Non-Compete Rule" on April 23, 2024
 - i. The Rule enumerated that, with respect both "senior executives" and "workers other than senior executives,"

noncompete agreements are “an unfair method of competition for a person”

- ii. The Rule made any effort to enforce a noncompete agreement a violations of Section 5 of the FTC Act and superseded “state laws that would ‘permit or authorize’ non-compete agreements.”

b. FTC staked its authority on two portions of FTC Act:

- i. Section 5 – “The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations . . . from using unfair methods of competition in or affecting commerce.”
- ii. Section 6(g) – Granted FTC power “to make rules and regulations for the purpose of carrying out the provisions of this subchapter.”

c. Plaintiff argued that Non-Compete Rule had no basis in the statute:

- i. The Act did not authorize Commission power to issue substantive unfair-competition rules
- ii. Prohibiting all workers from entering noncompete agreements is not a faithful reading of “unfair methods of competition”
- iii. FTC lacks statutory authority to invalidate already existing contracts

d. Defendant argued Congress provided broad mandate and everything in the Rule fell within FTC’s traditional expertise

- i. Congress provided FTC with broad mandate to police “unfair methods of competition” and that all rulemaking fell “squarely within the Commission’s delegated authority and expertise”
- ii. The Rule “is not unlawfully retroactive because it only has prospective effects”

3. Holding: Judge Brown, N.D. Tex., August 20, 2024

a. Applying *Loper*, Northern District of Texas held against FTC under plain interpretation of statute.

- i. “When authorizing legislative rulemaking, Congress also historically prescribes sanctions for violations of the agency’s rules—confirming that those rules create substantive obligations for regulated parties.”

- ii. “‘If the statute did not include a sanction, the authority to make ‘rules and regulations’ encompassed only interpretive or procedural rules.’”
- iii. “The Court concludes that the structure and the location of Section 6(g) indicate that Congress did not explicitly give the Commission substantive rulemaking authority under Section 6(g).”
- b. FTC appealed to 5th Cir. October 24, 2024, but Trump admin. contemplating dropping case

IV. **Recent Proof that the Agency Can Still Win Absent Chevron Deference**

a. *Becerra v. Empire Health Found.*, 597 U.S. 424 (2022) (Pre-Chevron)

- i. Issue
 - 1. What does it mean for a patient to be “entitled to [Medicare Part A] benefits” for purposes of computing hospitals DSH percentages.
- ii. Background
 - 1. The Medicare Fraction
 - a. The numerator reflects the number of the hospital’s patient days in which patients are entitled to SSI and Part A.
 - b. The denominator is the number of the hospital’s patient days in which patients are entitled to Part A.
 - 2. HHS position was that all patients enrolled in Medicare are “entitled to benefits under Part A” regardless of whether part A makes payment for a particular day
 - 3. The Hospital’s position was that only patients that are entitled to have their care covered during a particular day are “entitled to Part A benefits” for that day.
- iii. Holding, Justice Elena Kagan (June 24, 2022)
 - 1. Upheld HHS’s interpretation of “entitled to Part A benefits, as also including individuals who exhausted their benefits as the best interpretation of the statute without citing *Chevron*.
 - a. “[T]he Medicare statute uses the term ‘entitled’ to benefits in the same way as the Medicaid statute uses the term ‘eligible’ for benefits.”
 - b. “The entitlement to benefits, the statute repeatedly says, is an entitlement to payment under specified conditions. . . patients ‘who. . . exhausted their Medicare Part A inpatient coverage may still be entitled to other Part A benefits.’”

b. *Advocate Christ Medical Center, et al. v. Kennedy*, 605 U.S. ____ (2025)

i. Issue

1. Under what circumstances is a patient regarded as “entitled to [SSI] benefits” for purposes of the Medicare Fraction?
 - a. Agency’s Argument - The patient must receive *payment* from SSI that month.
 - b. Hospitals’ Argument – Comparable to *Empire*, it is sufficient merely that the patient is *eligible* for SSI payments and all patients enrolled in the SSI program should be included.

ii. Facts and Procedural Background of *Advocate Christ*

1. Over 200 hospitals filed appeals arguing that “entitled to [SSI]” should include all patients enrolled in the SSI program, even if they did not qualify for the monthly cash benefit.
2. Both the DDC and the DC Circuit endorsed HHS’s view that “[B]ecause SSI is a cash benefit, only a person who is actually paid these benefits can be considered ‘entitled’ to these benefits.”

iii. D.C. Circuit Decision

1. The D.C. Circuit rejected the providers’ argument that other benefits, and not just cash benefits, attributable to a patient’s SSI-eligible status should be considered.
2. “Entitled to [SSI]” refers to benefits provided under the SSI statute (Title XVI of the Social Security Act).
 - a. Medicare Part D is in Title XVIII and Ticket to Work is in Title XI.
3. Specifically, cash benefits.
 - a. “At every turn, [the SSI statute] is about cash payments for needy individuals who are aged, blind or disabled. Its title promises ‘supplemental security income’ for those individuals.”

iv. Holding, Justice Amy Coney Barrett (April 29, 2025) (Post-*Loper*)

1. “Because eligibility is determined on a monthly basis, an individual is considered ‘entitled to [SSI] benefits’ for purposes of the Medicare fraction only if she is eligible for such benefits during the month of her hospitalization.”

2. Court left open the question of whether CMS's current policy captures all patients that are "eligible" for SSI cash benefits in a particular month.

c. Amount of Deference is Irrelevant if Agency's Interpretation is Persuasive

- i. Two circuit courts held that increasing the wage index values of hospitals below the 25th percentile (at the expense of other hospitals) violated the plain meaning of the wage index statute:
 1. *Bridgeport Hosp. v. Becerra*, 108 F. 4th 882, (D.C. Cir. 2024).
 2. *Kaweah Delta Health District v. Becerra*, 123 F. 4th 939, (9th Cir. 2024).
- ii. However, in these cases the statute's plain meaning controlled but the court's level of deference was irrelevant.

1. Background

- a. In the IPPS final rule for FY 2020, CMS adopted a policy of increasing the wage index of "low wage index" hospitals, which it defined as hospitals with wage index adjustments below the 25th percentile nationwide. This is known as the low wage index hospital policy.
- b. Under this policy, CMS increased the wage index of low wage index hospitals by half the difference between the hospital otherwise final wage index and the 25th percentile wage index.
- c. CMS opted to implement the low wage index hospital policy in a budget neutral manner so that it would not increase aggregate IPPS expenditures. The agency believed this was required by the statute. But the agency noted that even if the statute did not require budget neutrality, it would have budget neutralized the policy anyway because "we would consider it inappropriate to use the wage index to increase or decrease overall IPPS spending."

2. Procedural History

- a. Many hospitals—particularly those with wage index values at or above the 25th percentile—vehemently opposed the low wage index hospital policy. Some of those hospitals promptly filed suit challenging the policy soon after it was adopted. They brought their case in the United States District Court for the District of Columbia.
- b. The D.C. District Court found for the hospitals. The government appealed to the D.C. Circuit.

3. Arguments

- a. Plaintiff Hospitals - The low wage index hospital policy violates the statutory command that the wage index factors must “reflect[] the relative hospital wage level in the geographic area of the hospital compared to the national average.” 42 U.S.C. § 1395ww(d)(5)(E)(i).
 - i. Because CMS had inflated the wage index factors of hospitals below the 25th percentile, the plaintiff hospitals contended that those factors did not “reflect” the wage levels of those hospitals compared with the national average.
- b. CMS - A long line of cases already deferred to CMS’s discretion to implement the wage index. In support of its plea for deference, the agency argued that the operative term “reflecting” is ambiguous and does not have precisely the same meaning as “equals.”
 - i. CMS also cited to the exceptions and adjustments provision of the statute as supplying the authority to adopt the low wage index hospital policy.

4. Holdings in *Bridgeport* and *Kaweah*

- a. Both courts held that the low wage index hospital policy violates the statute because it distorts the wage index.
 - i. D.C. Circuit
 - 1. “[T]he wage index factor must be anchored to a survey of wages and not other policy factors that would abandon or supplant the data-driven metric prescribed by Congress.”
 - 2. “[N]othing in the wage-index provision permits HHS to change those rates simply because it would rather give preferred hospitals more money and disfavored hospitals less.”
 - ii. Ninth Circuit
 - 1. “[T]he Wage Index Provision requires that the wage index ‘reflect’ HHS's best estimate of the relative wage levels of hospitals across the country—free from other policy goals that

distort, rather than reflect, the regional wage differences”

2. HHS has “stretched and twisted the plain meaning of the statutory text to pursue a policy objective not permitted under the statute.”

b. Both Courts also held that the “exceptions and adjustments” authority could at best be used to fill gaps left by Congress, but not to supplant Congress’s specific commands.

i. D.C. Circuit: The “‘exceptions and adjustments’ provision does not authorize HHS to set aside the congressionally required formula in the wage-index provision.”

ii. Ninth Circuit: “The broadly worded Exceptions and Adjustment Provision cannot swallow up the more specific Wage Index Provision.”

c. Both Courts also vacated the low wage index hospital policy.

i. D.C. Circuit: “[A]n agency can’t ‘cure’ the fact that it lacks authority to take a certain action.”

ii. Ninth Circuit: “HHS cannot correct its error on remand because the agency lacks statutory authority to promulgate the low-wage-index policy.”

d. HHS did not appeal either decision.

5. Fallout of *Bridgeport* and *Kaweah*

a. *Bridgeport* - HHS did not appeal case.

b. *Kaweah* - 60 and 90 day appeal window is closed, not appealed to the Supreme Court.

c. CMS revised the FY 2025 rule to remove the low wage index hospital policy from the 2025 rates

d. But CMS continues to include the low wage index hospital policy in calculating the OPPS rates.

i. “[T]he provision regarding calculation of the OPPS wage adjustment factor does not contain the same language that the D.C. Circuit found to be prescriptive for the calculation of the IPPS wage index”

- ii. OPPS statute “authorizes us to make adjustments to ‘ensure equitable payments.’”

V. How CMS Might Regulate in a Loper World

a. Considerations in Future Rulemaking

i. Potential Unintended Consequences

1. CMS likely will be more reluctant to improve its interpretations prospectively (as it did in *Lake Region* and some of the rural floor issues). This is because if CMS applies an interpretation that it recognizes is better prospectively, providers can argue that CMS is required to apply that better interpretation retroactively as well. CMS can no longer invoke the argument that its prior interpretation was still “reasonable” even if not the best.
2. Congress might include even more preclusion of review provisions.

ii. Though *Chevron* deference regarding statutory interpretation is gone, *Skidmore* deference regarding regulatory interpretation is still in effect:

1. When *Chevron* was in effect, it was like an on/off switch; an agency either received deference, or it did not.
2. *Skidmore* deference is more like a dimmer switch – courts can decide how much they require agencies to illuminate their reasoning and holding.

b. *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944)

i. Background

1. *NLRB v. Hearst Publications, Inc.*, 322 U.S. 111 (1944)

- a. Congress passed the National Labor Relations Act of 1935 empowering the National Labor Relations Board (NLRB) to protect the collective bargaining rights of “employees,” but not of “independent contractors.”
- b. Four Los Angeles newspapers refused to negotiate with a union representing “newsboys,” arguing that newsboys aren’t employees.
- c. The NLRB, the governmental plaintiff, determined in its own analysis that the term “employee” did in fact cover newsboys.
- d. “Where the question is one of specific application of a broad statutory term in a proceeding in which the agency administering the statute must determine it initially, the reviewing court’s function is limited.” *NLRB*, 322 U. S. at 131.

2. In *Skidmore*, seven plaintiffs employed as firefighters at a packing plant were paid for their overtime responding to overnight firearms, but not for their other overnight time.
 - a. Plaintiffs sought compensation for their unpaid overnight time.
 - b. The agency issued an “interpretive bulletin” that articulated a flexible standard for addressing when “on call” time should count as protected work and submitted an amicus brief that interpreted the FLSA to cover active (as opposed to sleeping) “on call” time.

ii. Issue

1. Is “on call” work covered by the minimum wage provision of the Fair Labor Standards Act?
2. How much deference should courts defer to the agency’s interpretation of law in its interpretive bulletin or amicus brief?

iii. Holding

1. Courts will give “great weight” to the “informed judgment” of an agency, but focus will shift to the agency’s “power to persuade”
 - a. While the agency’s determination will not control, “the rulings, interpretations and opinions of the Administrator . . . do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance.” *Skidmore*, 323 U.S. at 140.
2. The weight of courts’ deference to agency determinations depend on multiple relevant factors—
 - a. Thoroughness of agency’s consideration;
 - b. Validity of reasoning;
 - c. Consistency with earlier and later pronouncements; and
 - d. All factors which give it power to persuade.

iv. Significance for Post-Chevron Rulemaking

1. Commenters could influence an agency’s ability to persuade.
 - a. Courts may weigh whether or not the agency addressed all comments.
 - i. If agency has a thorough, valid, and consistent interpretation of disputed statutory text, *Skidmore* might gain increased significance in the post-*Loper* world.
 - ii. If agencies demonstrate a shifting, inconsistent, or bare-bones interpretation, they are less likely to access this additional deference.
 - b. Courts may evaluate the thoroughness of agencies’ responses to comments to determine whether to grant *Skidmore* deference.

2. OMB may play a more active role in reviewing proposed regulations and demonstrating the soundness and thoroughness of agencies' reasoning.
3. Courts may shift their focus to the non-delegation doctrine. *Skidmore* provides deference to agencies in interpreting general or broad statutory language, but if the language is too general or too vague, they may consider the legislature to be the right venue for deciding such questions, rather than agencies *or* the courts:
 - a.
 - b. Non-delegation doctrine. *See ALA Schechter Poultry Corp. v. United States*, 295 US 495, 529 (1935) ("Congress is not permitted to abdicate or to transfer to others the essential legislative functions with which it is thus vested.")

VI. *Loper* and ACA § 1557

a. May 2024 HHS Final Rule

- i. In May 2024, HHS promulgated a final rule that interpreted the ACA's § 1557 nondiscrimination language, "on the basis of sex," to include prohibiting discrimination on the basis of gender identity and sexual orientation.
- ii. Expected to go into effect on July 5, 2024, § 1557's expanded protections would have, among other things, prohibited the denial of gender-affirming care, provided protections for transgender insurance coverage, and compelled states to make gender-transition services available in Medicaid managed care plans. 89 Fed. Reg. 37522 (May 6, 2024).
 1. The final rule had a broad-reaching application, as all physicians who accept payment from Medicare Part B and ACA-covered providers would not be permitted to deny or limit health services related to gender transitioning or gender-affirming care based on an individual's sex or gender identity.

b. § 1557 Litigation

- i. States immediately sought injunctions to stop HHS from implementing and enforcing the final rule, using *Loper* to argue that HHS overstepped its authority in expanding the definition of sex and independent judicial interpretation was appropriate.
- ii. All courts faced with these requests have granted the injunctions, staying the gender identity provisions of the final rule.
- iii. *Tennessee v. Becerra*, 739 F. Supp. 3d 467 (S.D. Miss. 2024).
 1. Plaintiffs, 10+ states, argued that the HHS's interpretation of "on the basis of sex" exceeded statutory authority.

2. The court determined that the plaintiffs had a substantial likelihood of success on the merits, prefacing the discussion with *Loper*.
 - a. The court invoked the demise of *Chevron* in performing its own, independent statutory interpretation, noting that *Chevron* allowed agencies to change course even without congressional authority.
 - b. The court analyzed the HHS's interpretation by looking at the text, structure of the ACA, context, other statutory provisions, and legislative history to find that the HHS unreasonably conflated "on the basis of sex" with "on the basis of gender identity."
3. A nationwide injunction was issued staying the effective date, "in so far as [the] regulations are intended to extend discrimination on the basis of sex to include discrimination on the basis of gender identity." *Id.* at 485.
- iv. *Florida v. HHS*, 739 F. Supp. 3d 1091 (M.D. Fla. 2024).
 1. Florida and state agencies brought the same arguments in asking the court to enjoin the HHS from enforcing the final rule.
 2. The court cited *Loper* in performing independent statutory interpretation: "The new Rules must be legal; and no deference on matters of legality need be shown the agency." *Id.* at 1110.
 3. In issuing an injunction in Florida, the court reviewed the text and context of the statute, noting that the entire point of having a written statute is to have a fixed meaning at the time of enactment.
- v. *Texas v. Becerra*, 739 F. Supp. 3d 522 (E.D. Tex. 2024).
 1. Texas and Montana, likewise, argued that the HHS's interpretation exceeded its authority.
 2. The court again invoked the demise of *Chevron* and cited *Loper* to perform its own statutory interpretation. As the court declared, "How strangely will the tools of a tyrant pervert the plain meaning of words!" *Id.* at 528 (citation omitted).
 3. In issuing an injunction in Texas and Montana, the court used the text of the statute and its surrounding context to determine that "on the basis of sex" means only "on the basis of an individual's biological sex," not accounting for gender identity.
 - a. "[A]n agency has no authority to promulgate a rule that contradicts the language of the statute." *Id.* at 536.

c. Current Status

- i. In early 2025, the Trump Administration released multiple executive orders that aimed to reverse protections for gender identity/transgender healthcare and

rescinded former President Biden’s executive orders that aimed to prevent and combat discrimination on the basis of gender identity.

1. The Trump Administration also rescinded a March 2021 DOJ memo that stated the DOJ would apply the Supreme Court’s holding in *Bostock v. Clayton County*—that Title VII of the Civil Rights Act of 1964 protects employees against discrimination on the basis of sexual orientation or gender identity—in the context of Title IX (referenced by § 1557). 590 U.S. 644 (2020).
- ii. The HHS has also rescinded informal guidance documents related to gender affirming care, noting that “patient choice and individual freedom [should] dominate over burdensome federal regulations.” 90 Fed. Reg. 20393, 20394 (May 14, 2025).
- iii. However, even with the reversal in administrative policy, recissions, and nationwide injunction, the future of § 1557 is uncertain.
 1. The 2024 final rule was not yet in effect when injunctions were sought, and courts have noted that the final rule is still “[p]ending trial on the merits.”
 - a. *United States v. Skrmetti*, handed down on June 18, 2025, expressly “declin[ed] to address whether *Bostock*’s reasoning reaches beyond the Title VII context,” leaving open the utilization of *Bostock* in a case on the merits. No. 23-477, slip op. at 4 (U.S. June 18, 2025). However, *Bostock*’s reasoning was rejected in the Title IX *Loper* analysis of all three courts above.
 2. The HHS has not yet issued a nonenforcement policy or rescinded/replaced the rule through the notice-and-comment process.
 3. Thus, there could be challenges that continue to utilize *Loper* in the future if these cases ascend through the judicial system.

VII. Loper Implications on Fraud and Abuse

a. Preference for *Auer/Kisor* Deference?

- i. With *Loper* calling for courts to determine a statute’s single, best meaning, promulgated rules and guidance relating to healthcare fraud and abuse laws could be in question.
 1. For example, the Antikickback Statute (“AKS”), which prohibits knowing and willful financial payments/incentives to induce patient referrals or generate healthcare business, contains a wide range of statutory exceptions where remuneration is permissible.
 2. These exceptions have been expanded by HHS-OIG promulgating additional regulatory safe harbors.

3. However, even if plaintiffs bring *Loper* challenges, they are likely to be unsuccessful in the AKS regulatory safe harbor context, as 42 U.S.C. § 1320a-7b(b)(3)(E) expressly delegates the authority to the HHS Secretary to create regulatory safe harbors, which is a category where the court can defer to the agency to effectuate the will of Congress.
- ii. For example, one court has already addressed *Loper* in this AKS context and determined that *Loper* analysis did not apply to the HHS-OIG’s final rule regarding AKS safe harbor regulations.

1. *United States ex rel. Schroeder v. Hutchinson Reg’l Med. Ctr.*, No. 17-2060-DDC-BGS, 2024 WL 4298655 (D. Kan. Sept. 26, 2024).

2. Background

- a. Relator accused Hutchinson Regional Medical Center (“HRMC”) and Medtronic of violating AKS rules relating to bulk and bundled transactions when they engaged in medical device transactions. Specifically, Medtronic provided HRMC with directional atherectomy devices and additional drug-coated balloons for free alongside HRMC’s bulk drug-coated balloon purchase.

3. Arguments

- a. Relator argued that the defendants did not accurately document and report these bundled transactions and thus, the no-charge devices fall into AKS’s category of illegal remuneration.
- b. Defendants invoked both the AKS’s statutory discount exception and the corresponding regulatory safe harbor provision to argue that the transactions were legally protected.

4. Holding

- a. Summary judgment granted in favor of HRMC
 - b. The court used comment responses, preamble statements, and HHS final rules to rule in favor of HRMC.
 - i. In a footnote, the court acknowledged *Loper* but instead used *Auer* deference—the deference afforded when agencies interpret their own regulations.
 - ii. The court determined that the issue at hand did not involve a question of whether HHS acted within its statutory authority in promulgating final rules about the safe harbor for bundled transactions; instead, it involved a question of HHS’s interpretation of the same.
- iii. Another court followed a similar path in determining the meaning of “participating supplier” in a False Claims Act suit.

1. *United States ex rel. Olhausen v. Arriva Med., LLC*, No. 19-20190-Civ-Scola, 2025 WL 1659015 (S.D. Fla. June 12, 2025).
 - a. Relator alleged, through six causes of action, that the defendants submitted/conspired to submit fraudulent Medicare billing for diabetic and other medical supplies in violation of the False Claims Act.
 - b. Arguments
 - i. Relator alleged that the defendant was a “contract supplier” under a competitive billing program, which would cause it to collect assignments of claims from beneficiaries under Medicare.
 - ii. Defendant alleged that it was instead a “participating supplier,” that was not required to collect assignments.
 - c. Holding
 - i. The parties did not brief what CMS’s interpretation of “participating supplier” was, but the court found that the definition of the term was genuinely ambiguous through statutory interpretation.
 - ii. However, the court found that *Loper* deference did not apply. Instead, the court found that *Kisor* deference was applicable, because the question at issue was CMS’s interpretation of “participating supplier.”
 - iii. The court found that the defendant was required to collect assignments and was a “contract supplier,” for purposes of the motion to dismiss, but highlighted that the court could not decide whether CMS’s interpretation was reasonable.

b. *Loper*’s Applicability

- i. Some courts have requested additional briefing on *Loper* in the context of fraud and abuse cases filed before the *Loper* decision and have decided that *Loper* does apply to the case before them.
 1. *United States ex rel. Sheldon v. Forest Lab ’ys, LLC*, 754 F. Supp. 3d 615 (D. Md. 2024).
 - a. Background
 - i. A former employee of a prescription drug manufacturer brought this action for violations of the False Claims Act regarding an allegedly fraudulent reporting scheme under the Medicaid Drug Rebate Statute.
 - b. Arguments

- i. Relator claimed that Forest Laboratories failed to include certain customer price concessions in its calculation of “Best Price,” which requires manufacturers to offer the lowest price available during the rebate period.

- 1. Relator argued that CMS’s proposed rule on stacking discounts established falsity.

- ii. After an investigation, the United States declined to intervene, and the defendant moved to dismiss the suit.

- iii. The court ordered both sides to submit additional briefing on the impact of *Loper* on their case, if any.

c. Holding

- i. Relator failed to plead falsity and scienter as required by the FCA because the court found that the term “any entity” in the definition of “best price” was ambiguous and thus, could not establish scienter.

- ii. In its *Loper* analysis, the court rejected the claim that CMS’s proposed rule determined falsity, because “the Court would not be bound to accept as authoritative CMS’s construction of the Rebate Statute and Rebate Agreement.” *Id.* at 657.

- iii. The court did not defer to CMS’s interpretations of “Best Price.”

- 1. Explicitly, “The Court’s conclusions...in no way depend on or involve the exercise of deference to CMS’s interpretation of the Rebate Statute. Indeed, in the Court’s ruling regarding falsity, the Court has interpreted the Rebate Statute for itself.” *Id.* at 658.

c. *Loper* Challenges in the Future

- i. It may be easier for defendants to argue in False Claims Act suits that they could not have met the necessary scienter requirement of knowingly violating a regulation because their awareness of a regulation promulgated by the agency was not a valid interpretation of a governing statute.

- 1. This argument is bolstered by *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 749 (2023) (holding that the FCA’s scienter element refers to subjective knowledge and beliefs and “facial ambiguity alone is not sufficient to preclude a finding that respondents knew their claims were false”).

- 2. This argument thread is apparent in recent court decisions, like the District of Maryland holding that “regulatory pronouncements

regarding Medicaid drug rebate statute did not cure ambiguity in statute or rebate agreement between HHS and manufacturer to make manufacturer's familiarity with pronouncements sufficient to show that manufacturer acted with culpable mental state, as required for liability under FCA." *Sheldon*, 754 F. Supp. 3d at 615.

ii. At least one court has posited that *Loper* cannot be applied as a defense for anything other than interpreting an ambiguous statute.

1. *Kenley Emergency Med. v. Schumacher Grp. of La., Inc.*, No. 20-cv-03274-SI, 2025 WL 1359065 (N.D. Cal. May 9, 2025).

a. Defendants argued that the relator had to plead its claims with more particularity per the heightened scrutiny for fraud claims per Fed. R. Civ. P. 9(b) in a False Claims Act suit.

b. To do so, the defendants invoked *Loper*, arguing that *Loper* recognizes "the need for heightened clarity," so the plaintiff cannot rely on generalized allegations of "vaguely-described administrative guidance" to state a claim for fraud under the False Claims Act.

i. Memorandum in Support of Motion to Dismiss at 10–11, *Kenley*, 2025 WL 1359065 (No. 20-cv-03274-SI).

c. However, the court noted that an ambiguous statute must be in question to use any sort of *Loper* argument, and thus, this claim was without any merit.

iii. The application of *Loper* is still uncertain in some courts until further litigation materializes.

1. *United States v. Nelson*, No. 21-cv-05265-JFW-RAOx, 2025 WL 1165863 (C.D. Cal. Mar. 25, 2025).

a. In a False Claims Act suit, defendants, multiple care centers, argued that *Loper* required the district court to reevaluate deference to an agency interpretation of a statute that formed the basis of FCA claims, noting they were "entitled to a controlling presumption of validity as to all physician certifications of medical necessity." 2025 WL 1165863, at *6.

b. However, the court held that this presumption, whether correct or not, was not applicable or appropriate at the pleadings stage and declined to both preemptively address the *Loper* argument and certify an interlocutory appeal to the Ninth Circuit regarding the same until a factual record was developed.