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Featured Article

The Future of Deference to Health Care Sub-Regulatory Guidance Under *Kisor v. Wilkie*

Zubin Khambatta

ABSTRACT: In *Kisor v. Wilkie*, a divided Supreme Court upheld the doctrine, first announced in *Bowles v. Seminole Rock & Sand Co* and later upheld in *Auer v. Robbins*, that directs federal courts to defer to an agency's reasonable interpretation of its own regulations when resolving ambiguities in the meaning of those regulations. This article assesses the implications of that decision for the practice of health care law in the administrative law and regulatory areas. Justice Kagan's majority opinion lays out a complex checklist of threshold factors that courts must examine to determine the appropriate approach for addressing issues concerning potential ambiguities in regulations. Her opinion raises the question of whether *Auer/Seminole Rock* deference has now been refashioned to be equivalent to its putative competitor—the doctrine announced in *Skidmore v. Swift & Co* that courts must review agency interpretations of regulatory ambiguities but defer to them only to the extent the soundness of such interpretations has persuasive authority. As a result of *Kisor*, the force and effect of sub-regulatory guidance issued by health care agencies may be more precarious and subject to challenge. At the same time, regulatory agencies may react to such developments by altering the form and procedures used to issue regulatory interpretations and may even pull back from their reliance on sub-regulatory guidance as a policy tool. Health care attorneys should stay abreast of how federal courts interpret and apply *Kisor* due to the opportunities and challenges it may introduce for efficacious legal representation and advocacy.

Zubin Khambatta, *The Future of Deference to Health Care Sub-Regulatory Guidance Under Kisor v. Wilkie*, J. Health and Life Sci. L., Oct. 2020, at 8. © American Health Law Association, www.americanhealthlaw.org/journal. All rights reserved.

The Future of Deference to Health Care Sub-Regulatory Guidance

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INTRODUCTION

Health care attorneys work in regulatory areas that are often flooded with "sub-regulatory guidance"—prescriptive rules or instructions issued by a federal or state health agency that interpret that agency's own regulations. These interpretations can, among other things, fill regulatory gaps, clarify vague regulatory provisions, involve the declaration of policies regarding how formal legal rules will be enforced, and reflect policy choices driven by shifts in political incumbency, legal developments, market trends, the emergence of new technologies or market actors, or broader changes in political norms or aspirations.

The U.S. Department of Health and Human Services (HHS) alone houses 11 operating divisions or agencies that include the Centers for Medicare & Medicaid Services (CMS), the Food & Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Indian Health Service (HIS), and the National Institutes of Health (NIH). These agencies issue a vast array of sub-regulatory guidance, such as preamble commentary in proposed regulations, responses to comments in the preamble of final rules, manuals, bulletins, fraud alerts, FAQs, letters, webpages, online portals, instructions, webinars, PowerPoints, program applications, policy guidance, advisory opinions, and national and local coverage determinations. In addition, more informal sub-regulatory guidance in the form of press releases, statements at press conferences or on conference calls, and pronouncements at meetings also matter in setting expectations about how agencies will interpret and enforce their regulations and statutory mandates. To support positions taken in litigation, moreover, agencies offer regulatory interpretations for the first time in court proceedings, or else adopt interpretations in litigation that they have failed to issue in some type of guidance document or otherwise widely publicize.

It is no small exaggeration to say that much of a health care attorney's time is devoted to monitoring, parsing, and applying such statements of how regulatory agencies interpret their own regulations. This is often the key to understanding how that same agency will enforce these regulations—what conduct it will and will not go after and on what grounds. Much in the way of providing efficacious legal counsel to the health care community depends on understanding these dynamics.

BACKGROUND ON THE DOCTRINE OF *AUER* DEFERENCE EXAMINED IN *KISOR V. WILKIE*

Enter *Kisor v. Wilkie*.[1] The Supreme Court granted *certiorari* in *Kisor* for one reason: to decide whether to jettison the federal administrative law doctrine commonly known as *Auer* deference.[2] Under *Auer*, if the meaning of a federal regulation is ambiguous, federal courts are to give a federal agency's clarifying interpretation "controlling weight" if not "inconsistent

1 Kisor v. Wilkie, 139 S. Ct. 2400 (2019).

2 *Id*. at 2408.

with the regulation" or "plainly erroneous."[3] This doctrine is at times also referred to as *Seminole Rock* deference as it originates from the Court's 1945 opinion in *Bowles v. Seminole Rock & Sand Co.*[4]

Auer deference implicates the core distinction made in the Administrative Procedure Act (APA) between "legislative rules" and "interpretive rules."[5] Agencies must promulgate legislative rules through notice-and-comment rule-making,[6] and the APA provides that they have the "force and effect of law."[7] In contrast, agencies can issue interpretive rules in a myriad of ways without following the notice-and-comment process.[8] The price the APA exacts for this simplicity is that interpretive rules lack the "force and effect of law."[9] Such interpretations are conventionally understood to provide guidance and clarity on how an agency will enforce its own regulations and, by extension, the governing law of the agency's purview.[10] But the agency's view of when a legal rule has been violated is not the same thing as the legal rule's authoritative meaning, even when the agency created that rule.[11]

When addressing agency interpretations of regulations, therefore, courts are to first ask whether the interpretation addresses a bona fide ambiguity in the underlying legislative rule.[12] If the legislative rule is clear on the point in question, then it should be followed.[13]

But if it is not, the question becomes how a court should address an administrative agency's resolution of that ambiguity via an interpretive rule it has issued. Should the court simply defer to that interpretation in the absence of some over-riding reason to do otherwise? Or should it interpret the underlying legislative rule with fresh eyes (*i.e.*, engage in *de novo* review)? Should the agency follow what it concludes to be the best interpretation, even if the agency's differing interpretation is not patently incorrect, and may even be quite reasonable?

Auer's answer is grounded in favoring the competency of administrative agencies over courts to resolve such issues.[14] Under *Auer*, courts should defer to an agency's interpretation of regulations provided that the interpretation does not contradict the regulation's clear meaning and that the interpretation is not otherwise clearly erroneous.[15]

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3 Auer v. Robbins, 519 U.S. 452 (1997).
4 Bowles v. Seminole Rock & Sand Co., 325 U.S. 410 (1945).
5 *See* Administrative Procedure Act, 5 U.S.C. § 553 (2020).
6 *See id*. § 553(b) & (c).
7 Perez v. Mortg. Bankers Ass'n, 575 U.S. 92, 96 (2015) [hereinafter *Mortg. Bankers*] (citing Chrysler Corp. v. Brown, 441 U.S. 281, 302–03 (1979)).
8 *See* 5 U.S.C. § 553(b)(3)(A); *Mortg. Bankers*, 575 U.S. at 96.
9 *Mortg. Bankers*, 575 U.S. at 97 (citing Shalala v. Guernsey Mem'l Hosp., 514 U.S. 87, 99 (1995) [hereinafter *Shalala*]).
10 *Mortg. Bankers*, 575 U.S. at 97 (citing *Shalala*, 514 U.S. at 99).
11 *Mortg. Bankers*, 575 U.S. at 97 (citing *Shalala*, 514 U.S. at 99).
12 Kisor v. Wilkie, 139 S. Ct. 2400, 2410–14 (2019).
13 *Id*. at 2415.
14 Auer v. Robbins, 519 U.S. 452, 461–63 (1997).
15 *Id*. at 461–63.

The principal alternative to this view stems from the Court's 1944 decision in *Skidmore v. Swift & Co.*[16] Under *Skidmore*, an agency's interpretations of ambiguous regulations are "not controlling upon the courts."[17] Courts should still carefully consider an agency's regulatory interpretations to resolve ambiguities. But rather than controlling weight, *Skidmore* compels that these interpretations should be afforded only a weight proportional to the "thoroughness evident in [the agency's] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade...."[18] In Justice Gorsuch's view, moreover, those who hold to an originalist theory of legal interpretation would view "the government's early, longstanding, and consistent interpretation of a statute, regulation, or other legal instrument could count as powerful *evidence* of its original public meaning" where the "original public meaning" is the foundational standard for determining the meaning of legal rules.[19] In sum, agency interpretations serve as no more and no less than an important resource for what meaning the agency's regulation should be afforded. Courts should follow their own determinations of the best and most fair-minded readings of those regulations even when they conflict with an agency's own interpretation of those regulations.

The Facts of *Kisor*

At issue in *Kisor* was a Department of Veterans Affairs (VA) regulation allowing retroactive disability benefits if the "relevant official service department records" were presented by an applicant that were not considered at the time a veteran's initial application was denied.[20] Kisor applied for disability benefits in 1982, claiming that he suffered from post-traumatic stress disorder (PTSD) from serving in the Vietnam War. The VA concluded that Kisor did not suffer from PTSD at the time of his initial application and denied his claim. When Kiser reopened his claim in 2006 on the basis of a new psychiatric report, he sought disability benefits accruing from 1982—the date of his original claim. Although the VA reversed its earlier decision, it elected to only grant him benefits from the date he reopened his claim in 2006, not the date when he initially filed for benefits in 1982.[21]

Kisor appealed this determination to the VA's administrative court—the Board of Veterans' Appeals (the "Board"). On appeal Kisor produced two new service records that confirmed his participation in combat operations. But the Board determined these new records were not "relevant" to the denial of Kisor's claim because they did not speak to the basis for the agency's conclusion regarding whether Kisor has PTSD. Rather these service

16 Skidmore v. Swift & Co., 323 U.S. 134 (1944), *abrogated by* Bowles v. Seminole Rock & Sand Co., 325 U.S. 410 (1945); Auer v. Robbins, 519 U.S. 452 (1997).

17 *Id*. at 140.

18 323 U.S. at 140.

19 Kisor v. Wilkie, 139 S. Ct. 2400, 2426 (Gorsuch, J. concurring) [hereinafter *Kisor*].

20 *See* 38 C.F.R. § 3.156(c)(1) (2020).

21 *Kisor*, 139 S. Ct. at 2408–09.

records were relevant to the separate question of whether Kisor engaged in combat in the first place, an issue that was not in dispute. For these reasons the Board affirmed the VA's denial to Kisor of retroactive benefits dating back to 1982.[22]

On appeal from the Board's decision, the Court of Appeals for the Federal Circuit found that the regulation in question was ambiguous.[23] It could reasonably be read to mean that "relevant" records were limited to those casting doubt on the agency's original rationale for a denial, as the VA argued. Or, as Kisor claimed, what is "relevant" could reasonably be interpreted to include those records that relate to the veteran's claim *en toto*, and not just to the basis for the VA's prior determination. Given that the regulation at issue was susceptible to two reasonable interpretations, the Federal Circuit sided with the agency on the basis of the straight-forward application of *Auer* deference.[24] Kisor appealed and requested the Supreme Court to overturn *Auer*.

The Court's Decision

In an opinion written by Justice Kagan, the Court declined Kisor's invitation by a bare 5-4 majority.[25] Justice Kagan and the four Justices joining her in the majority—Chief Justice Roberts and Justices Ginsburg, Breyer, and Sotomayor—upheld the *Auer* doctrine on the ground of *stare decisis*.[26] These same four Justices concurred in that part of Justice Kagan's opinion that set forth several constraints on when federal courts can apply *Auer* deference to an agency's regulatory interpretations.[27] These parameters may serve to substantially cut back on the level to which federal courts will defer to an agency's interpretations of its own regulations.

In an opinion concurring with the Court's decision to vacate and remand the lower court's judgement, Justice Gorsuch authored a scathing rebuke to Justice Kagan that delineated the reasons for scuttling *Auer* deference.[28] Justice Thomas joined the entirety of that opinion, while Justices Kavanaugh and Alito joined it in part. Chief Justice Roberts issued a separate concurring opinion in which he claimed that there was "much in common" between the Court's decision to uphold a more scrutinizing form of *Auer* (call it *Kisor* deference) and Justice's Gorsuch's position that *Auer* should be over-turned so as to allow courts to decide regulatory issues based on their understanding of the "best and fairest reading" of the regulations in question.[29] Justice Kavanaugh also issued a concurring opinion where he expressed his agreement with the Chief Justice's view about the similarities between Justice Kagan's scrutinizing form of *Auer* deference and Justice Gorsuch's view that *Skidmore* should prevail.[30]

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22 *Id*. at 2409.
23 *Id*.
24 *Id*.
25 *Id*. at 2422–23.
26 *Id*.
27 *Id*. at 2414–18.
28 *Id*. at 2425–48.
29 *Id*. at 2424–25.
30 *Id*. at 2448–49.

THE JURISPRUDENTIAL UNDERPINNINGS OF *AUER*

As Justice Kagan explained in a plurality section of her opinion, *Auer/Seminole Rock* deference is based on a presumption about Congressional intent—what has been more candidly referred to by scholars as a "fictional" presumption about Congress' intent.[31] This presumption is that when Congress in a federal statute grants an agency the power to promulgate regulations to concretize the statute's prescriptions into a governing body of rules, it concomitantly intends for an agency's reasonable interpretations to resolve issues over the meaning of ambiguous terms in those regulations.[32] The presumption is rebuttable, and Justice Kagan's opinion in *Kisor* contains an articulation of when that presumption can be rebutted.[33]

The deeper presumption at work here is that in most cases Congress has not deliberated over—much less expressed in a statute—its position on the question of whether it prefers agencies or courts to decide issues of ambiguous regulatory meaning.[34] The presumptive intent in favor of agency deference is therefore a fiction as well as a choice over a competing fictitious presumption that Congress intended courts to engage in *de novo* review of ambiguous regulations along the lines of the *Skidmore* approach.

When viewed as a fictional, presumed intent, two theoretical underpinnings of *Auer/Seminole Rock* deference are brought into relief.

First, the choice of fictions and thus the choice of a deferential versus a *de novo* interpretive method "operates principally as a background rule of law against which Congress can legislate."[35] The Court's proponents of *Auer* never question the power of Congress to expressly dictate whether courts should interpret a particular body of regulations *de novo*, defer to an agency's reasonable interpretations of ambiguities within those regulations, or take up some other approach.[36] *Auer/Seminole Rock* deference places the ball in Congress's court to instruct the federal courts to leave aside deference to agency interpretations of ambiguous regulations by passing an amendment to the APA or a specific statute that requires them to engage in *de novo* review.[37]

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31 *See id*. at 2412 (citing Martin v. Occupational Safety & Health Review Comm'n, 499 U.S. 144, 151–53, (1991) [hereinafter *Martin*]); Cass R. Sunstein & Adrian Vermeule, *The Unbearable Rightness of Auer*, 84 U. Chi. L. Rev. 297, 305–07 (2017), http://lawreview.uchicago.edu/sites/lawreview.uchicago.edu/files/14%20Sunstein Vermeule_SYMP_IC.pdf [hereinafter Sunstein & Vermeule].

32 *Kisor*, 139 S. Ct. at 2412 (citing *Martin*, 499 U.S. at 151–53).

33 *Kisor,* 139 S. Ct. at 2412, 2415–18.

34 *See* Sunstein & Vermeule, at 305–07. *See also* Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law*, 1989 Duke L.J. 511, 515–17 [hereinafter Scalia], https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=3075&context=dlj (discussing how deference to agency regulations that address statutory ambiguities under Chevron, U.S.A., Inc. v. NRDC, Inc., 467 U.S. 837 (1984) is based on the fiction that Congress intended for agencies to resolve such questions).

35 *See* Sunstein & Vermeule, at 305–07. *See also* Scalia, at 515–17 (making the similar point with respect to *Chevron* deference).

36 *See Kisor*, 139 S. Ct. at 2422–23.

37 *See id*.

The second underpinning of *Auer* is that as a matter of good judicial policy courts should presume that Congress in general wants courts to defer to an agency's interpretations of regulatory ambiguities because they are more likely to correctly resolve such questions.[38]

In *Kisor* the Court took up the question of whether this latter presumption is sound. Given Congress has wide latitude to change the rules of the interpretive game, which doctrine includes the better of the (fictional) presumptions about Congressional intent—*Auer* or *Skidmore*?

Justice Kagan's View of Why *Auer* Deference Should Remain

In the opinion for the Court' s majority, Justice Kagan explained both how *stare decisis* considerations weighed against over-ruling *Auer* and *Seminole Rock* and how the deference they compel must be limited. Relying on *stare decisis*, she explained that *Auer* was supported by a long line of precedents, not just a few; that dispensing with *Auer* would lead to re-litigation of several cases that relied on this doctrine to settle the construction of regulations; and that Congress was always free to upend *Auer's* presumption and mandate *de novo* review of agency interpretations.[39]

In her plurality opinion, Justice Kagan discussed at length why *Auer* and not *Skidmore* is the correct answer to the question of whether Congress should be presumed to prefer agencies or courts to resolve genuine interpretive conflicts. Due to limitations of space, only three of the more significant of these reasons can be discussed here.

First, Justice Kagan argued that an agency is better positioned to discern the meanings of regulations that it drafted and promulgated. Justice Kagan articulated this as a proposition about authorial intent: "Want to know what a rule means? Ask its author."[40] Administrative law scholars have noted that although this assumes a controversial theory of interpretation, namely that the proper interpretation of a legal text involves discerning the intentions of its authors, this rationale is stronger when the interpretation at issue was issued not long after the regulation.[41] But when an agency has changed its interpretation or the question at issue involves interpreting term that the agency has not previously focused upon, this particular argument carries less weight.[42]

Second, the resolution of regulatory ambiguities often involves decisions about what is most sound public policy, and agencies are better positioned than courts to make those

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38 *See id*. at 2412–14.

39 *Id*. at 2422–23.

40 *Id*. at 2412.

41 *See* Aditya Bamzai, Comment, *Delegation and Interpretive Discretion: Gundy, Kisor, and the Formation and Future of Administrative Law*, 133 Harv. L. Rev. 164, 196–98 (2019), https://harvardlawreview.org/wp-content/uploads/2019/11/164-199_Online.pdf.

42 *Kisor*, 139 S. Ct. at 2412.

determinations.[43] The presumption that Congress intended *Auer* deference recognizes this reality. Agencies have the following advantages over courts:

- "unique expertise," often of a scientific or technical nature, relevant to applying a regulation "to complex or changing circumstances;"
- the ability to conduct factual investigations;
- the ability to consult with affected parties;
- the ability to consider how their experts have handled similar issues over the long course of administering a regulatory program; and
- greater political accountability as a result of being subject to the supervision of the President, who in turn answers to and is elected by the public.[44]

In short, *Auer/Seminole Rock* deference is justified as a mechanism for selecting the policy expertise of administrative agencies over the courts.

Third, the *Auer/Seminole Rock* presumption promotes the rule of law value of uniformity in addressing the interpretation of ambiguous regulations as compared to the piecemeal resolutions that would result if courts took the leading role in this arena.[45] Justice Kagan emphasized that this justification is strongest "in the context of a 'complex and highly technical regulatory program.'"[46] "After all," explains Justice Kagan, "judges are most likely to come to divergent conclusions when they are least likely to know what they are doing."[47]

Justice Gorsuch's View that *Auer* Should Be Replaced by *Skidmore* Deference

Justice Gorsuch provides several reasons for over-ruling *Auer/Seminole Rock* and returning to *Skidmore's* emphasis on the persuasive weight of agency interpretations. Again, due to limitations of space, only four of these are discussed here.

First Justice Gorsuch argues that *Auer/Seminole Rock* is inconsistent with the APA.[48] Section 706 of the APA states:

> To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and ***determine the meaning or applicability of the terms of an agency action*** . . . The reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . .

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43 *Id*. at 2413.
44 *Id*. at 2413.
45 *Id*. at 2413–14.
46 *Id*.
47 *Id*. at 2414.
48 *Id*. at 2432–33.

Justice Gorsuch seized on this language to conclude that deference to an agency's regulatory interpretation that a reviewing court finds inferior amounts to an abdication of the duty under the APA to determine the meaning or applicability of the terms of an agency action and to "set aside agency action . . . not in accordance with law."[49] According to Justice Gorsuch, the APA demands that courts engage in meaningful and substantive judicial review of all agency actions including the regulations it promulgates, while *Auer* deference contravenes this edict by compelling them to engage in cursory and formalistic judicial review when deciding the controlling meaning of an agency's regulations.[50]

Further, in Justice Gorsuch's view *Auer* deference collapses the APA's distinction between legislative rules and interpretive rules.[51] According to Justice Gorsuch, *Auer* requires courts to treat interpretive rules as if they had the force and effect of law even though they were not subject to the notice-and-comment process.[52] Effectively this allows agencies to amend their regulations without going through the notice-and-comment process required by the APA.[53]

Second, Justice Gorsuch argues that the notion of grounding *Auer* in the presumed intent of Congress is incoherent in light of the APA's directive that courts must engage in full-fledged judicial review of agency regulations without first seeing if they must defer to the agency's interpretations of these regulations.[54] Justice Kagan claims that when the APA was enacted by Congress in 1946, Section 706 was understood to restate the then current law regarding the scope of judicial review of agency action, and that law included the Court's 1945 decision in *Seminole Rock*.[55] Although agreeing that the Attorney General at the time expressed such an opinion, Justice Gorsuch points to other authorities, including Congressional reports on the APA, that expressed the alternative view that this legislation was intended to empower courts over agencies in deciding questions of what the law means.[56]

Third, Justice Gorsuch argued that *Auer* is incompatible with the exclusive vesting of the judicial power in the Supreme Court and the lower federal courts under Article III, § 1 of the Constitution.[57] This principle entails that neither the legislative nor executive branches can usurp the judicial power that the Constitution reserves to the federal courts.[58] And, according to Justice Gorsuch, it is grounded in the fundamental commitment that judicial independence is a bulwark of the rule of law and its concomitant protection against the arbitrary use of government power and preservation of the ability to assert one's rights and obtain a fair hearing before a neutral court.[59] *Auer* mandates that a court follow the executive branch's

49 *Id*.
50 *Id*.
51 *Id*. at 2434–35.
52 *Id*. at 2435.
53 *Id*.
54 *Id*. at 2435–36.
55 *Id*. at 2419–20.
56 *Id*. at 2436.
57 *Id*. at 2437–39.
58 *Id*. at 2438.
59 *Id*. at 2439.

interpretation of the law rather than the judiciary's fairest and best reading.[60] It therefore allows self-interested and politically motivated agencies to unite the powers of making, enforcing, and interpreting law in the hands of a single authority, thereby undermining the values of the rule of law and the civil liberty that the Constitution's separation of powers is established to protect.[61]

Fourth, Justice Gorsuch noted that even if regulations are typically not designed to be vague, as Justice Kagan claimed, ambiguities in their meaning frequently arise.[62] By unduly restricting the judgment of courts, *Auer* impinges on the ability of parties to receive a fair hearing over interpretive disputes.[63] It also disincentivizes agencies from using notice-and-comment procedures although doing so would produce better policy because of the ability for the public to provide input.[64]

KISOR DEFERENCE: A MORE SCRUTINIZING FORM OF *AUER*

In her opinion for the majority, Justice Kagan announced the Court's ruling on when and how *Auer/Seminole Rock* deference applies. This discussion stresses the limits on *Auer* deference, reflecting the Court's concern that courts were reflexively and mechanically deferring to agency interpretations of regulations rather than engaging in a scrutinizing inquiry as to whether such deference was appropriate.[65] To remedy that situation, Justice Kagan set out a series of guidelines that effectively re-makes *Auer* into a more scrutinizing form of deference. These guidelines are:

1. The regulation at issue must be "genuinely ambiguous" after a court has "exhaust[ed]" all traditional tools of interpretation—including text, structure, history, and purpose of a regulation.[66]

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60 *Id*.

61 *Id*. at 2438–39.

62 *Id*. at 2440–41.

63 *Id*. at 2441.

64 *Id*. at 2440–41. Justice Gorsuch also countered a number of Justice Kagan's other arguments for upholding *Auer*. In doing so, he claimed, among other things: (1) the public meaning of an agency's rules and not the promulgating agency's intent is the proper standard for interpreting regulations (*Id*. at 2441); (2) the notion that resolving regulatory ambiguities is more a question of policy than traditional legal exegesis is incorrect and undermines the basic premise that the American people are governed by written laws and not the policy preferences of agency officials (*Id*. at 2442); (3) to the extent that agencies have unique technical expertise that should inform the interpretation of regulations, this can be adequately accounted for under the *Skidmore* approach (*Id*. at 2442–43); (4) *Auer* does not have an advantage in promoting uniformity and stability in the law over courts; the judicial process can produce uniform interpretations of the law, while agencies can quickly change their interpretations (*Id*. at 2443); (and 5) for the following reasons, *stare decisis* does not justifying upholding Auer: (a) *Auer*'s breadth, lack of merit, and failure to generate valid reliance interests, (b) the growth of the administrative state, and (c) over-ruling *Auer* will not cause a significant amount of re-litigation of settled interpretive disputes (*Id*. at 2443–47).

65 *See id*. at 2414–15.

66 *Id*. at 2415.

2. The agency's reading of an ambiguous regulation must be "reasonable" to fall "within the zone of ambiguity the court has identified after employing all its interpretive rules."[67] In short, the interpretation may not conflict with or contravene the regulation's clear meaning.
3. The court must make an independent inquiry as to "whether the character and context of the agency interpretation entitles it to controlling weight."[68] This inquiry does not involve a single exhaustive test, but instead involves a review of the following "markers:"
   a. the regulatory interpretation must be the agency's authoritative or official position;
   b. the agency's interpretation must be based on its substantive expertise;
   c. the agency's interpretation must reflect its "fair and considered judgment;" convenient litigating positions or "*post hoc* rationalizatio[n] advanced to defend past agency action against attack" do not qualify; and
   d. the agency must not be advancing a new interpretation that creates "unfair surprise" to regulated parties; examples of such unfair surprise are the issuance of an interpretation that conflicts with the agency's preceding interpretation and the new issuance of an interpretation that forbids some longstanding conduct that was previously allowed.[69]

67 *Id*. at 2415–16.

68 *Id*. at 2416 (citing Christopher v. SmithKline Beecham Corp., 567 U.S. 142, 155 (2012); United States v. Mead Corp., 533 U.S. 218, 229–31, 236–37 (2001)).

69 *Kisor*, 139 S. Ct. at 2416–18.

These factors may lead a court to conclude that Congress would not have wanted courts to defer to an administrative agency's interpretation of a regulatory ambiguity even if that interpretation is a reasonable reading of the underlying regulation.[70]

Chief Justice Robert's View Regarding the Close Similarity Between the *Kisor* Majority and Justice Gorsuch

Chief Justice Roberts wrote separately to convey that there is much in common between the scrutinizing form of *Auer* articulated by Justice Kagan and the *Skidmore*-based standard favored by Justice Gorsuch:

> The majority catalogs the prerequisites for, and limitations on, Auer deference: The underlying regulation must be genuinely ambiguous; the agency's interpretation must be reasonable and must reflect its authoritative, expertise-based, and fair and considered judgment; and the agency must take account of reliance interests and avoid unfair surprise. Justice Gorsuch, meanwhile, lists the reasons that a court might be persuaded to adopt an agency's interpretation of its own regulation: The agency thoroughly considered the problem, offered a valid rationale, brought its expertise to bear, and interpreted the regulation in a manner consistent with earlier and later pronouncements. Accounting for variations in verbal formulation, those lists have much in common.[71]

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70 In writing for the plurality, Justice Kagan gave additional reasons for upholding a more scrutinizing form of *Auer*. She argued that Auer does not conflict with section 706 of the APA by requiring courts to abdicate their responsibility to determine the meaning and applicability of the terms of agency action (*Id*. at 2418–19). Among other reasons, she explained that courts must exhaust traditional methods of interpretation in determining whether deference is appropriate due to regulatory ambiguity and that section 706 allows courts to engage in *Auer's* reasonableness standard of review as well as *de novo* review (*Id*. at 2419). Her opinion also asserts that *Auer* does not conflict with section 553's requirement that legislative rules be promulgated by notice-and-comment. Courts applying *Auer* must still determine whether an agency's interpretive rules should be controlling. Therefore it is the courts—not the agencies—that are imbuing these rules with the force and effect of law (*Id*. at 2420–21). She also asserts rejects for lack of no evidence the academic theory that *Auer* incentivizes agencies to strategically craft vague regulations that then afford them wide latitude in governing through interpretive clarifications (*Id*. at 2421). She also explained that *Auer* does not violate the Constitution's separation of powers. In her view, courts retain a firm grip on interpretive authority by engaging in the scrutiny that *Auer* requires. Therefore, *Auer* does not result in courts abandoning the judicial function for the executive branch to take over (*Id*.). Finally, in response to the argument that *Auer* involves the unconstitutional combination of the federal government's three branches in the executive department, Justice Kagan's rebuttal is that such comingling it is endemic to the nature of the executive function and has occurred since the beginning of the Republic (*Id*. at 2421–22). It therefore does not violate the separation of powers (*Id*.).

71 *Id*. at 2424.

Is there Daylight any Longer between *Auer* and *Skidmore*?

In a concurring opinion, Justice Kavanaugh agreed with Chief Justice's Roberts position.[72] According to him and Chief Justice Roberts, the more scrutinizing form of *Auer* deference reflected in *Kisor* is very close to *Skidmore* deference—which requires courts to examine the agency's basis and rationale for a given interpretation and determine whether they are sufficiently persuasive to "defer" to that interpretation.[73] Along these lines, Justice Gorsuch allowed for the possibility that "[t]he majority leaves Auer so riddled with holes that, when all is said and done, courts may find that it does not constrain their independent judgment any more than *Skidmore*."[74]

Ultimately, it remains to be seen whether *Kisor* ushered in an era where courts will go considerably farther than just refraining from reflexively deferring to sub-regulatory guidance. *Kisor* raises the prospect that courts will in practice give very little deference to agencies and will consistently operate under the view that sub-regulatory guidance is a useful but not controlling resource for reaching the correct interpretations of ambiguous regulations.

CONCLUSION

Kisor's most obvious implications are that federal courts will on the whole give less deference to agencies' interpretations of their own regulations and that it will make such sub-regulatory guidance more vulnerable to challenges in court.

Beyond that, there is a question to which markers now part of the *Auer* deference framework will courts gravitate to decide that deference is not warranted. It seems unlikely in most cases that courts would find that an interpretation is not based on the agency's particular expertise. The natural presumption would be that agencies have expertise in the areas they regulate for the simple reason that the basic organization of the administrative state is based on this premise. It seems likely that only in cases involving highly unusual circumstances would it be possible to overcome this presumption. Demonstrating that a particular interpretation did not involve the agency's fair and considered judgment also seems unlikely, although perhaps not as high a hurdle as showing that an agency lacks expertise in the area at issue.

In contrast, a claim that an interpretation is not the agency's authoritative position or that it involves unfair surprise involve considerations that courts could more readily seize upon to deny deference. In both cases, courts can look to factors that are relatively objective with pertinent information that judges can more readily ascertain.

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72 *Id*. at 2448.

73 *See* Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944) ("We consider that the rulings, interpretations and opinions of the Administrator under this Act, while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance. The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.").

74 *Kisor*, 139 S. Ct. at 2448.

Another issue is how agencies will respond to *Kisor*, if at all, from an *ex ante* perspective. Will agencies adjust their regulatory procedures so as to issue interpretations that conform to *Kisor's* guidelines about what merits deference? Will, for example, agencies avoid releasing interpretations that emanate from informal mechanisms or lower level officials and instead exert greater effort to ensure interpretations bear the imprimatur of being an official position? Will agencies take greater care to avoid the regulatory "flip-flops" that occur when they issue interpretations that conflict with prior interpretations? Will agencies go to greater lengths to base their interpretations on technical expertise? If so, will this effort be more in the form of *post-hoc* window-dressing to shield an interpretation from legal attack, or will it be driven by a more sustained and focused effort to base policy on knowledge, expertise, and analysis?

Relatedly, will *Kisor* cause agencies to shift more to regulating via formal, notice-and-comment rule-making as opposed to the issuance of regulatory interpretations? Given the shakier ground that *Kisor* puts under agency interpretations, one might think this is a coming trend. But agencies may also pursue a strategy of issuing relatively low-cost regulatory interpretations and then waiting to see if serious legal challenges arise. If they do, then as back-up agencies can effectuate their policy choices through the more costly mechanism of formal regulations.

Another consideration is that from the perspective of regulated parties, agency interpretations are far from being uniformly unwelcome. Regulated parties often seek the clarity that these interpretations bring. Relying on notice-and-comment procedures for this purpose may be undesirable. These procedures can take much longer than the time frame in which guidance is wanted, and they make more wholesale reform of a regulatory regime more likely although such broader changes are unwanted. Given that the economic interests and other preferences of regulated parties often diverge, *Kisor* increases the risk of relying on regulatory interpretations deemed favorable. Even when a particular interpretation is unfavorable, *Kisor* may make it more costly and uncertain for that regulated party to plan and execute "work around" strategies.

Overall, health care attorneys should pay close attention to how *Auer/Kisor* deference develops as the lower federal courts apply the *Kisor* framework. Further, health care counsel will want to pay attention to the following:

1. Is sub-regulatory guidance ripe for legal challenge under the more scrutinizing form of *Auer* articulated in *Kisor*?
2. How will *Kisor* affects an agency's willingness to enforce a particular regulatory interpretation? Will enforcement be more selective? Would it be beneficial to directly challenge a regulatory interpretation by relying on *Kisor*?
3. How can *Kisor* be strategically deployed in more informal ways? For example, should informal demands be made on regulatory agencies to issue interpretations that are based on a more careful and thorough review of their scientific or evidentiary basis so as to be considered an exercise of fair and considered judgment? Should interpretations be informally challenged on such grounds after they are issued? Will *Kisor* ultimately cause agencies to issue better informed sub-regulatory guidance?

4. Under what circumstances can agencies change their substantive views on what is and is not legally allowed or mandated via issuing revised interpretations or new sub-regulatory guidance? Is sub-regulatory guidance that existed prior to *Kisor* now less likely to be superseded by new agency interpretive pronouncements because of concerns raised by the Court, such as unfair surprise?
5. How does one determine in this context when unfair surprise occurs? This seems easier when an agency seeks to announce new requirements or restrictions by replacing one official interpretive rule with another. But what about situations when an agency allows a certain pattern of conduct to go on for several years? Is it unfair surprise if the agency issues sub-regulatory guidance that now makes such conduct a violation of some pre-existing regulation?
6. Although Justice Kagan dismissed the idea that agencies engage in strategic ambiguity when crafting regulations, is that the case? Should regulated parties expect less ambiguity in regulations? If parties request through notice-and-comment that agencies clear up ambiguities in proposed regulations and those ambiguities persist in the final version, will subsequent interpretations that clarify those ambiguities be more vulnerable to attack under *Kisor*?

Finally, there is the very real prospect that in response to *Kisor* agencies will shift their efforts away from sub-regulatory guidance toward formal rulemaking, at least in certain instances. That development would underscore the importance of *Chevron, U.S.A, Inc. v. Natural Resources Defense Council*, which calls for deference to the interpretation of a statute reflected in an agency's regulation when a court addresses a dispute over the meaning of ambiguous statutory language.[75]

Chevron deference raises issues that are similar to those raised by *Auer*.[76] Although beyond the scope of this essay, it is worth noting that *Chevron* serves as a second and perhaps stronger line of an agency's defense against attacks to their regulatory authority. If agencies can simply rely on *Chevron* deference to accomplish their policy objectives, then *Kisor's* medium to long-term significance may not be very great. Agencies can have formal rules at the ready should their sub-regulatory guidance be challenged. But that in itself may be momentous. Formal rules require notice-and-comment. Regulated parties may therefore have much greater opportunity to comment on the rules under which they are governed, and may have considerably more advance notice and time to prepare for changes in these rules before they are issued. This may be *Kisor's* most significant legacy.

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75 Chevron, U.S.A., Inc. v. NRDC, Inc., 467 U.S. 837, 844 (1984).

76 *See* Cass R. Sunstein & Adrian Vermeule, *The Unbearable Rightness of Auer,* 84 U. Chi. L. Rev. 297, 305–07 (2017); Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law*, 1989 Duke L.J. 511. *But cf.* Talk Am., Inc. v. Mich. Bell Tel. Co., 564 U.S. 50, 68, 131 (Scalia, J., concurring) (explaining that other than through enacting more precise statutes, Congress cannot control the rule-making authority given to executive agencies to implement ambiguous statutes, while *Auer* recognizes the power of agencies to both write regulations and control their subsequent implementation through sub-regulatory guidance).

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