[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 19-11876

D.C. Docket No. 1:19-cv-01783-AT

RANDALL CALLAHAN,
KATRYNA GRISSON,
CANDICE SEAMAN,
MICHAEL WINGATE,
EMORY UNIVERSITY,
d.b.a. Emory University Hospital,
HENRY FORD HEALTH SYSTEM,
INDIANA UNIVERSITY HEALTH,
OREGON HEALTH & SCIENCE UNIVERSITY,
PIEDMONT HEALTHCARE,
THE RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA,
on behalf of its Medical Center,
THE REGENTS OF THE UNIVERSITY OF MICHIGAN,
on behalf of its academic medical center, Michigan Medicine,
SAINT LUKE'S HOSPITAL OF KANSAS CITY,
UNIVERSITY OF IOWA,
UNIVERSITY OF KANSAS HOSPITAL AUTHORITY,
a body politic and corporate and an independent instrumentality of the State of Kansas,
UNIVERSITY OF KENTUCKY,
VANDERBILT UNIVERSITY MEDICAL CENTER,
VIRGINIA COMMONWEALTH UNIVERSITY HEALTH SYSTEM AUTHORITY,
THE WASHINGTON UNIVERSITY,

BARNES-JEWISH HOSPITAL,

Plaintiffs - Appellants,

versus

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
through ALEX M. AZAR II in his official capacity as
Secretary of the United States Department of Health
and Human Services,
UNITED NETWORK FOR ORGAN SHARING,

Defendants - Appellees,

SUSAN JACKSON,
CHARLES BENNETT,

Intervenor Appellees.

Appeal from the United States District Court
for the Northern District of Georgia

(September 25, 2019)

Before WILSON and NEWSOM, Circuit Judges, and COOGLER,[*] District Judge.

NEWSOM, Circuit Judge:

The liver is one of the human body's most vital and versatile organs. Among its 500-some-odd functions, the liver cleans the blood, regulates amino acids, produces critical proteins, manages blood clotting, and facilitates digestion.

[*] Honorable L. Scott Coogler, United States District Judge for the Northern District of Alabama, sitting by designation.

But that's when things go right. Far too often—and due to a variety of causes—things can go wrong, and when they do modern medicine has to step in. For minor liver complications, medication and dietary changes will usually do the trick. When liver failure sets in, though—when things go *really* wrong—there is often only one long-term solution: transplant.

This case centers on the high-stakes rules that determine which patients—among the more than 12,000 currently on the national waiting list—receive the liver transplants they need. In December 2018, a private nonprofit entity tasked by the Department of Health and Human Services (HHS) with coordinating the nation's organ-transplant system adopted a new policy for allocating donated livers. This suit followed. Plaintiffs, four liver-transplant candidates and more than a dozen transplant hospitals, challenged the policy in federal district court on a variety of grounds and moved for preliminary injunctive relief barring the policy's implementation. The district court denied the motion, and plaintiffs filed an interlocutory appeal.

The central question we face is one of regulatory construction. In particular, we must determine whether 42 C.F.R. § 121.4(b) required the Secretary of HHS to take two procedural steps that all agree he did not: (1) referral of the new liver-allocation policy to an entity called the Advisory Committee on Organ Transplantation and (2) publication of the new policy in the Federal Register for

public comment. We hold that the Secretary was not required to do so, and we therefore affirm—at least in that regard—the district court's denial of plaintiffs' preliminary-injunction motion. Because the district court failed to address two of plaintiffs' claims, however, we remand for consideration of them in the first instance.

I

Before diving into the merits, we first need to canvass the statutory and regulatory landscape, some factual background, and the case's procedural posture. Fair warning: This gets complicated.

A

In the United States, organ transplants are a public-private affair. The National Organ Transplant Act of 1984 requires HHS to appoint and oversee the Organ Procurement and Transplant Network (OPTN)—a private nonprofit responsible for coordinating foundational aspects of the nation's organ-transplant system. *See* 42 U.S.C. § 274. Under the Act, the OPTN must maintain a list of transplant candidates, implement a system for allocating donated organs, and ensure the organs' equitable distribution. *See id.* § 274(b).

While the Act describes the OPTN's duties in broad strokes, HHS's implementing regulation—the "Final Rule"—covers the nitty-gritty, from the OPTN's Board of Directors to its record-maintenance policy. *See* 42 C.F.R.

§§ 121.1–.13. Most importantly for present purposes, the Final Rule prescribes the procedures that the OPTN must follow when developing new organ-transplant policies, as well as the circumstances under which—and extent to which—HHS must review those policies. *See id.* § 121.4.

We'll get *way* down into the regulatory weeds in due time, complete with a dense block quote of the Final Rule's pertinent text—but for now it's enough to summarize the Rule's key features. As an initial matter, the Final Rule states that whenever the OPTN proposes any new policy, its Board of Directors must give OPTN members and other "interested parties" an opportunity to comment on it, and the Board must "take [those comments] into account" in developing and adopting the policy. *Id.* § 121.4(b)(1). Separately, the Rule requires the OPTN to provide the Secretary of HHS with two types of proposed policies at least 60 days prior to their intended implementation: (1) those that the OPTN Board "recommends to be enforceable"[1]; and (2) those that relate to "such other matters as the Secretary directs." *Id.* at § 121.4(b)(2). Finally, as part of the same subsection—and as you'll see soon enough, this is where the debate hinges—the

[1] A bit of additional background: None of the OPTN's adopted policies are, in and of themselves, legally "enforceable" against members of the transplant community; rather, compliance is strictly voluntary. But the OPTN can recommend to the Secretary that he or she *make* a policy enforceable. If the Secretary does so, any entity that violates the policy risks an enforcement action to terminate its participation in Medicare or Medicaid. 42 C.F.R. § 121.10(c)(1). So far, that hasn't been necessary. The OPTN has never asked the Secretary to make one of its organ-allocation policies enforceable; voluntary compliance has been excellent.

Final Rule requires the Secretary to refer "significant proposed policies" to the Advisory Committee on Organ Transplantation and to publish those policies in the Federal Register for "public comment." *Id*.

B

An organization called the United Network for Organ Sharing has served as the OPTN for the past 35 years. In 2013, United Network approved and implemented the liver-allocation policy that remains in place today. The current policy distributes livers based on two geographic criteria: "Regions"—11 groups of states—and "Donation Service Areas" (DSAs)—58 smaller, geographically irregular areas (within and among states) that surround the entities that United Network has tasked with collecting donated organs.[2]

In recent years, the use of DSAs has come under fire. Critics of the DSA-based system contend that because DSAs are neither geographically uniform nor designed to minimize transit of donated organs, reliance on them can lead to bizarre allocation results. They argue, for instance, that organs can end up

[2] Under the current policy, a donated liver is first matched and offered to patients who are Status 1A or 1B—the most gravely ill—*and* who reside in the DSA or Region where the liver is acquired. If there is no suitable match, the liver is then offered to patients—again, who reside in the same DSA or Region where the liver is acquired—based on their Model for End-Stage Liver Disease (MELD) score, which rates patients from 6 (least ill) to 40 (most ill). If there are no matching candidates in the DSA or Region with a MELD score of 15 or higher, the liver is then offered to outside candidates.

traveling greater distances to less-sick patients.[3] Defenders of the DSA-based system, by contrast, insist that aligning organ allocation with the organ-procurement organizations encourages communication between the entities that collect organs and those that perform transplants.

By 2016, United Network had decided that things needed to change. After more than a year of exploring alternatives, United Network approved a new liver-allocation policy in December 2017. That policy—which retained DSAs but reduced their impact on allocation decisions—was set to take effect in December 2018. In May 2018, however, a group of patients awaiting liver transplants filed a comment with the Secretary pursuant to 42 C.F.R. § 121.4(d)[4] criticizing *any* continued use of DSAs in liver-allocation determinations. Two months later, in July 2018, the Secretary instructed United Network's Board to scrap the December 2017 policy and adopt a new one that eliminated the use of Regions and DSAs altogether.

[3] Consider the following example, used as an illustration at oral argument: Under the current, DSA-based policy, if a liver becomes available in Charleston, South Carolina, it would be offered to a moderately ill patient in Memphis, Tennessee (600 miles away) before a critically ill patient in Atlanta, Georgia (266 miles away)—and indeed, would have to be flown directly over Atlanta en route to Memphis.

[4] "Any interested individual or entity may submit to the Secretary in writing critical comments related to the manner in which the OPTN is carrying out its duties or Secretarial policies regarding the OPTN." 42 C.F.R. § 121.4(d). The Secretary must then "seek, as appropriate, the comments of the OPTN on the issues raised in the comments" and must "consider the comments in light of the [Act] and the [Final Rule]." *Id.*

United Network went back to the drawing board, but it faced an extremely tight timeline. The Secretary's July 2018 instruction imposed a December 3, 2018 deadline for promulgating the new liver-allocation policy. By September, the Liver and Intestinal Transplantation Committee—a specialized group within United Network that makes recommendations to the Board—had homed in on two alternative, DSA-less approaches for allocating livers: the "Acuity Circles" model and the "Broader 2-Circle" model.[5] When the Committee published its policy proposal on October 6, it identified the Broader 2-Circle model as the "preferred" policy, but it sought public comment on both options. At the Committee meeting on November 2, the Broader-2 Circle model prevailed by a narrow 11-9 vote.

United Network's Board, however, went the other way. On December 3, 2018—the HHS-imposed deadline—the Board adopted the Acuity Circles model. This model, the Board found, would result in "lower waitlist mortality rate[s]" and "more equity in access" for liver-transplant candidates. United Network later set the policy's implementation date for April 30, 2019.

[5] The Acuity Circles model draws concentric circular boundaries at 150, 250, and 500 nautical miles from the donor hospital. The model then offers the donated liver based on the following hierarchy: (1) Status-1 candidates within the 500-mile circle; (2) candidates with MELD scores of at least 37 within the 150-mile circle, then the 250-mile circle, then the 500-mile circle; (3) candidates with MELD scores between 33 and 36 within the 150-mile circle, then the 250-mile circle, then the 500-mile circle; (4) candidates with MELD scores between 15 and 28 within the 150-mile circle, then the 250-mile circle, then the 500-mile circle. The Broader 2-Circle model uses the same distance-based circles, but places a premium on proximity—it gives lower priority to candidates with greater medical urgency who are farther away from the donor hospital.

Up to this point, HHS had remained on the sidelines. Of course, the Secretary had initiated the process by directing United Network to adopt a new, DSA-less allocation policy. But once the new policy's development began, HHS didn't actively intervene. As particularly relevant here, consistent with HHS's treatment of prior organ-allocation policies, the Secretary didn't refer the new policy to the Advisory Committee on Organ Transplantation or publish it in the Federal Register for public comment.

The new policy's detractors, however, brought HHS into the mix. Just as critics of the December 2017 policy had done, a group of hospitals that opposed the new policy filed a comment with the Secretary asking him to suspend the new policy's implementation until something better could be developed. This time, though, the policy survived the challenge. Acting on the Secretary's behalf, the Administrator of HHS's Health Resources and Services Administration responded to the comment, announcing that no further action was warranted and that the new policy would take effect as scheduled.

C

On April 22, 2019—eight days before the new policy's official implementation date—a collection of hospitals and individual patients sued HHS and United Network in the United States District Court for the Northern District of

Georgia.[6] Plaintiffs' complaint challenged the new liver-allocation policy on three grounds: (1) that HHS failed to follow legally required procedures during the development of the new policy, in violation of the Administrative Procedures Act (APA); (2) that HHS's and United Network's actions were—both substantively and procedurally—arbitrary, capricious, and otherwise not in accordance with the law, also in violation of the APA; and (3) that HHS's and United Network's conduct violated the Due Process Clause of the Fifth Amendment. Asserting the same grounds, plaintiffs also filed a motion for a temporary restraining order, asking the district court to prevent the new policy's impending implementation.[7]

Following HHS's agreement to delay implementation by two weeks, the district court received expedited briefing and held a hearing on plaintiffs' TRO motion. On May 13, 2018, the district court—in an order that addressed only plaintiffs' first claim—denied the motion. The following day, the new liver-allocation policy went into effect for the first time. Its force, however, was short lived. Plaintiffs immediately noticed this appeal and sought an injunction pending

[6] Shortly after the complaint was filed, two liver-transplant candidates—Susan Jackson and Charles Bennett—sought to intervene as defendants. Holding that Jackson and Bennett (who, in July 2018, had brought suit in the Southern District of New York seeking to invalidate the current liver-allocation policy) had "established a significant interest in the subject matter of this litigation," the district court granted their motion to intervene under Federal Rule of Civil Procedure 24(b).

[7] The district court construed plaintiffs' TRO motion as also requesting a preliminary injunction, in accordance with Federal Rule of Civil Procedure 65.

its disposition, which the district court granted. As a result, HHS reinstated the prior (and once again current) policy.

So here we are. After years of development, thousands of public comments, and several revisions, the nation's policy for allocating donated livers hangs in the balance.

II

The standard for obtaining preliminary injunctive relief is a familiar one. Such relief is appropriate if—but only if—the movant shows "(1) substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest." *McDonald's Corp. v. Robertson*, 147 F.3d 1301, 1306 (11th Cir. 1998). Because a preliminary injunction "is an extraordinary and drastic remedy," relief may not be granted "unless the movant clearly established the burden of persuasion as to the four requisites." *Id.* (internal quotation marks and citation omitted).[8]

Our task on appeal is to determine whether the district court erred in concluding that plaintiffs failed to satisfy their burden and were therefore ineligible

[8] We review the district court's ultimate decision to deny plaintiffs' motion for abuse of discretion, but we examine any constituent legal conclusions *de novo*. *See United States v. Endotec, Inc.*, 563 F.3d 1187, 1194 (11th Cir. 2009).

for preliminary injunctive relief. We begin (and for now find that we can end) with plaintiffs' first claim—the only one that the district court addressed. In particular, the district court concluded that plaintiffs had failed to demonstrate a substantial likelihood of success on the merits of their contention that HHS neglected to follow legally required procedures during the new liver-allocation policy's development. We hold that the district court was right in so concluding, if not quite for the right reasons. As for plaintiffs' second and third claims—respectively, that defendants' actions in adopting the new policy were arbitrary and capricious and deprived plaintiffs of due process—we will remand so that the district court can consider them in the first instance.

A

Now, for the promised deep dive into 42 C.F.R. § 121.4(b)—the section of the Final Rule that we summarized earlier. Section 121.4(b) contains two subsections; its relevant text is as follows:

> (b) The [OPTN] Board of Directors shall:
>
> > (1) Provide opportunity for the OPTN membership and other interested parties to comment on proposed policies and shall take into account the comments received in developing and adopting policies for implementation by the OPTN; and
> >
> > (2) Provide to the Secretary, at least 60 days prior to their proposed implementation, proposed policies it recommends to be enforceable under § 121.10 (including allocation policies). These policies will not be enforceable until approved by the Secretary. The Board of Directors shall also provide to the

> Secretary, at least 60 days prior to their proposed implementation, proposed policies on such other matters as the Secretary directs. ***The Secretary will refer significant proposed policies to the Advisory Committee on Organ Transplantation established under § 121.12, and publish them in the Federal Register for public comment.*** The Secretary also may seek the advice of the Advisory Committee on Organ Transplantation established under § 121.12 on other proposed policies, and publish them in the Federal Register for public comment. . . .

42 C.F.R. § 121.4(b) (emphasis added).

Plaintiffs' first claim centers on a single sentence of § 121.4(b)(2)—which we've italicized and which, to keep matters straight here, we'll call the "significant proposed policies" sentence. Plaintiffs' contention is simple and straightforward: Clearly, they say, a policy that fundamentally alters liver-allocation procedures throughout the country is "significant." And because it's undisputed that the Secretary neither referred the new liver-allocation policy to the Advisory Committee nor published it in the Federal Register—as, on plaintiffs' reading, the significant-proposed-policies sentence requires—it follows that the Secretary violated § 121.4(b)(2).

Defendants see it differently. They argue that, properly understood, § 121.4(b)(2)'s significant-proposed-policies sentence doesn't apply here at all. Under defendants' reading, the significant-proposed-policies sentence's referral and publication requirements are triggered *only* in the two circumstances specified in § 121.4(b)(2)'s opening clauses: (1) when the policy at issue is one that the

OPTN's Board "recommends to be enforceable"—we'll call this (more than a little clunkily) the "recommends to be enforceable" sentence—or (2) when the policy at issue is one that relates to "such other matters as the Secretary directs"—here, the "as the Secretary directs" sentence. Because it's undisputed that neither of those two conditions obtained here, defendants contend, the Secretary wasn't required to refer the policy to the Advisory Committee or publish it in the Federal Register.

Boiled to its bare essence, then, the interpretive question we face is whether § 121.4(b)(2)'s referral and publication requirements apply to *all* "significant proposed policies" (plaintiffs' reading) or, instead, only to those "significant proposed policies" that (1) the OPTN's Board has "recommend[ed] to be enforceable" or (2) pertain to a matter that the Secretary has "direct[ed]" (defendants' reading). In short: Does § 121.4(b)(2)'s significant-proposed-policies sentence stand alone, such that it applies universally, or is it modified and limited by § 121.4(b)(2)'s recommends-to-be-enforceable and as-the-Secretary-directs sentences?

The district court answered this question in defendants' favor. Deferring to HHS's interpretation of § 121.4(b)(2), that court held that plaintiffs had not demonstrated a substantial likelihood of success on their claim that the Secretary was legally obligated to refer the new liver-allocation policy to the Advisory Committee or publish it in the Federal Register. *See* Amended Dist. Ct. Order at

10–11. We agree with the district court's bottom-line conclusion—and we therefore affirm that court's decision that plaintiffs haven't shown the requisite substantial likelihood of success on their first claim—but we arrive at that conclusion by a different route. As the Supreme Court recently held in *Kisor v. Wilkie*, deference "is not the answer to every question of interpreting an agency's rules." 139 S. Ct. 2400, 2414 (2019).[9] This case illustrates the truth and wisdom of that observation. Here, we hold that the "traditional tools of construction"—which *Kisor* directs reviewing courts to "exhaust" before resorting to principles of deference, *id.* at 2415—provide a clear answer: Defendants' reading of § 121.4(b)(2) is the better one.

1

a

We begin, as always—and as *Kisor* reiterates we should—with "text [and] structure." *Id.*; *see also Chase Bank USA, N.A. v. McCoy*, 562 U.S. 195, 204 (2011). To orient ourselves, let's start with the big(ish) picture—a bird's-eye view.

[9] *Kisor* was issued just before the close of briefing in this case—the day before plaintiffs' reply brief was due, in fact. In response to this Court's request, though, the parties filed supplemental briefs addressing the effect, if any, that *Kisor* should have on this case. We are confident, therefore, that the parties had full opportunity to litigate *Kisor*'s applicability. We are equally confident that a *Kisor*-based remand to the district court is unnecessary. Although the district court didn't have the benefit of the Supreme Court's decision, *Kisor* itself disclaims any groundbreaking. *See* 139 S. Ct. at 2410 ("You might view this Part"—describing the regime of regulatory interpretation and deference associated with *Auer v. Robbins*, 519 U.S. 452 (1997)—"as 'just background' because we have made many of its points in prior decisions."); *see also id.* at 2418 (noting that its articulation of *Auer* restated "longstanding doctrine").

Section 121.4(b)'s two subsections lay out two possible paths for the review and development of proposed organ-transplant policies. Path number one—§ 121.4(b)(1)—provides for the usual, baseline OPTN-administered notice-and-comment review. Subsection (b)(1) places no limitation on the "proposed policies" to which it applies—it requires OPTN's Board to give both "OPTN membership and other interested parties" an opportunity to comment on *all* proposed policies, irrespective of substance, and then directs the Board to consider those comments in developing and adopting the policies for implementation. Path number two—§ 121.4(b)(2), which governs the Secretary's involvement in and review of proposed policies—is different, right off the bat. Unlike subsection (b)(1), subsection (b)(2) immediately narrows in on two subsets of policies: (1) those that OPTN's Board "recommends to be enforceable" and (2) those that relate to "other matters as the Secretary directs." Those two types of proposed policies—and *only* those—must be provided to the Secretary at least 60 days prior to their intended implementation. 42 C.F.R. § 121.4(b)(2).

Even before getting into the details—and addressing the significant-proposed-policies sentence and its placement in subsection (b)(2)—we should pause to consider what § 121.4(b)'s two-path architecture indicates. It seems, we think, to imply a "default-and-extra"-style regime, with subsection (b)(1) being the "default" and subsection (b)(2) being the "extra." In other words, it suggests—not

definitively so, but presumptively—that the baseline (b)(1) requirements apply to all proposed organ-allocation policies, while the additional (b)(2) requirements apply only to a subset of those policies.

With that structural context in mind, let's zoom back in to take a closer look at § 121.4(b)(2) itself—and in particular, the way in which its several constituent sentences interact. A careful reading, we think, confirms that defendants' interpretation is the better one—subsection (b)(2), including the significant-proposed-policies sentence and its referral and publication requirements, applies only to two specific types of proposed policies: those that OPTN's Board "recommends be enforceable" and those pertaining to matters that the "Secretary directs." That is so for at least three reasons.

First, and most fundamentally, there's the "scope-of-subparts" canon, pursuant to which, at least as a general proposition, "[m]aterial within an indented subpart relates only to that subpart." Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 156 (2012); *see also*, *e.g.*, *Lary v. Trinity Physician Fin. & Ins. Servs.*, 780 F.3d 1101, 1105–06 (11th Cir. 2015) ("Ordinarily, the scope of a subpart is limited to that subpart . . . ."). Under this interpretive principle, the significant-proposed-policies sentence's placement within subsection (b)(2) indicates that it goes with, relates to, and is limited by the

other sentences in that subsection, including the recommends-to-be-enforceable and as-the-Secretary-directs sentences.[10]

Second, we think that is the most natural—and most coherent—reading of § 121.4(b)(2). Subsection (b)(2) operates like a flow chart—or, as it was described at oral argument, a "funnel" that begins wide and narrows as it goes. The first few sentences mark out the universe of proposed policies to which § 121.4(b)(2) applies—at the risk of repetition, those that OPTN's Board "recommends to be enforceable" and those that relate to "matters [that] the Secretary directs." Subsection (b)(2) expressly requires that such proposed policies be provided to the Secretary for his review 60 days in advance of their implementation. Having received a proposed policy that fits one of those two descriptions, the Secretary must then determine whether it constitutes a "significant proposed polic[y]." 42 C.F.R. § 121.4(b)(2). If he concludes that it does, he "will"—must—refer it to the Advisory Committee and publish it in the Federal Register for public comment. *Id.* With respect to "other proposed policies"—*i.e.*, those that he determines are not "significant"—the Secretary "may," but need not, refer and publish them. *Id.* On defendants' reading, therefore, the significant-proposed-policies sentence slots in

[10] To be sure, where it "makes no sense" to interpret language as being limited to the subpart in which it appears, the scope-of-subparts canon can give way. *Lary*, 780 F.3d at 1106. For reasons explained in the body, however, that isn't the case here. Quite the contrary, in fact.

comfortably with the sentences that come before and after it—all links in a continuous chain of administrative review.

Finally, defendants' reading isn't just natural, it's also sensible. As just explained, § 121.4(b)(2) requires that two particular types of policies be sent to the Secretary at least 60 days prior to their "proposed implementation"—*i.e.*, before they are slated to go into full force and effect. Presumably, there's a reason that those two—and no others—are singled out that way. If we read the ensuing significant-proposed-policies sentence as applying—as § 121.4(b)'s text and structure indicate—only to those two, the reason becomes clear: For "significant proposed policies" that either OPTN's Board has "recommend[ed] to be enforceable" or pertain to a matter that the Secretary has "direct[ed]," the Secretary *must* take certain action—in particular, he must refer them to the Advisory Committee and publish them in the Federal Register. Of course, doing so—all in advance of the date of "proposed implementation," *id.*—requires *time*. Under defendants' reading of § 121.4(b)(2), the recommends-to-be-enforceable and as-the-Secretary-directs sentences work hand-in-hand with the significant-proposed-policies sentence: they operate, together, to ensure that the Secretary will have enough time to do what needs to be done.

If (as plaintiffs insist) HHS had meant for the significant-proposed-policies sentence to apply beyond the two types of policies flagged at the outset of

subsection (b)(2), surely it would have given *some* textual indication. HHS could, for instance, have placed the significant-proposed-policies sentence *before* the recommends-to-be-enforceable and as-the-Secretary-directs sentences. That might have signaled that the significant-proposed-policies sentence applied to *all* proposed policies, rather than only a subset of them. HHS also could have created a separate subsection for the significant-proposed-policies sentence. A clear break from the recommends-to-be-enforceable and as-the-Secretary-directs sentences would have communicated that the significant-proposed-policies sentence embodies a distinct, stand-alone requirement. It might (?) even have been possible for HHS to keep the significant-proposed-policies sentence in its current location but to say, straight out, that its referral and publication requirements apply to proposed policies beyond those identified in the recommends-to-be-enforceable and as-the-Secretary-directs sentences—something like, "The Secretary will consider all policies proposed by the OPTN and will refer those that he deems significant . . . ."

But HHS didn't do any of those things. Instead, it chose to place the significant-proposed-policies sentence immediately following the recommends-to-be-enforceable and as-the-Secretary-directs sentences. Given that choice, the significant-proposed-policies sentence is read most naturally—and in accordance

with the scope-of-subparts canon and common sense—as being modified and limited by those two preceding sentences.

b

Against all of this, plaintiffs raise two textual arguments—neither of which convinces us. First, plaintiffs point out that when the significant-proposed-policies sentence is read alone, it more naturally supports their reading than defendants'. Maybe so—there's nothing within the four corners of the significant-proposed-policies sentence itself that clearly limits its application to the policies referenced in the recommends-to-be-enforceable and as-the-Secretary-directs sentences. But as enticingly straightforward as plaintiffs' argument may be, it's just not how we read law—tidbits and fragments in isolation. *See, e.g.*, *Strickland v. Water Works & Sewer Bd. of City of Birmingham*, 239 F.3d 1199, 1204–05 (11th Cir. 2001) (refusing to construe regulatory terms "absent their context"); Scalia & Garner, *supra*, at 167 ("Context is a primary determinant of meaning."). And for reasons we've explained in detail already, when read in toto—and in context—§ 121.4(b)(2) is best understood as limiting the significant-proposed-policies sentence's referral and publication requirements to policies that fit within the recommends-to-be-enforceable and as-the-Secretary-directs sentences.

Second, plaintiffs invoke the presumption of consistent usage. Under this canon of construction, a word or phrase is presumed to bear the same meaning

throughout a text. *See* Scalia & Garner, *supra*, at 170. Plaintiffs assert that § 121.4(b)(1) uses the same term that § 121.4(b)(2)'s significant-proposed-policies sentence uses—"proposed policies"—to mean *all* proposed policies. According to plaintiffs, adopting defendants' interpretation would mean giving the term "proposed policies" a different, narrower meaning in § 121.4(b)(2)—one that it bears nowhere else in the text. The response to all of this is basically, "See above." Although the presumption of consistent usage has its place, it also "readily yields to context." *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 320 (2014) (internal quotation marks and citation omitted) (holding that the Clean Air Act's definition of "air pollutant" includes greenhouse gases but that the term had a narrower, context-dependent meaning when it appeared in a section of the statute addressing permits). And here, read in context, the phrase "proposed policies" in § 121.4(b)(2) is most logically limited by the sentences that precede it within the same subsection.

* * *

Based on the preceding analysis, we hold that defendants' interpretation of § 121.4(b) is demonstrably superior to plaintiffs'. Not only is defendants' reading more natural, given the rule's format, but it also coherently harmonizes the rule's several constituent provisions. Plaintiffs' interpretation, by contrast, wrenches

§ 121.4(b)(2)'s significant-proposed-policies sentence out of context and depends on a wooden literalism that we cannot accept.

2

Because § 121.4(b)'s text is clear, we needn't consult extra-textual evidence concerning "history" and "purpose." We address these considerations briefly, however, because they featured so prominently in plaintiffs' briefing and because, given the circumstances, we think it prudent to cover the waterfront. *See NLRB v. SW Gen., Inc.*, 137 S. Ct. 929, 941–42 (2017) (declaring the statutory text "clear," but nevertheless considering history- and purpose-based arguments to show why they were "not compelling").

The Final Rule (codified in relevant part at 42 C.F.R. § 121.4(b)) was first published in the Federal Register in 1998 and then amended—to its current language—in 1999. In conjunction with each of the Rule's two iterations, HHS published a statement that purported to describe the agency's motivations. The parties cite to these statements extensively, so we consider them in turn.

First, the 1998 Rule. Plaintiffs seize on language from HHS's 1998 statement, which they insist demonstrates an intent to require broad agency review of OPTN policies: "The Secretary also recognizes the need for additional public participation in the development of some OPTN policies, such as fundamental revisions to organ allocation policies." 63 Fed. Reg. 16,301. And later: "While

we believe that the comment process administered by the OPTN itself is invaluable in obtaining technical advice, it does not reach all of the affected public . . . or otherwise provide the functions and protections accorded by the impartial review by the Secretary." *Id.* at 16,310.

But as defendants emphasize, the same HHS statement also appears to give the Secretary broad discretion to determine how OPTN policies should be reviewed. Just after "recogniz[ing] the need for additional public participation," HHS's statement observes that the Final Rule accordingly "*enable[s]* the Secretary to seek comment from the public and to direct the OPTN to revise policies *if necessary*." *Id.* at 16,301 (emphasis added). What's more, the statement goes on to explain that there is often good reason for the Secretary to employ a more modest system of review: "A body of voluntary standards that can be rapidly revised, particularly for purely technical changes, is a crucial function of the OPTN system and one that the Secretary strongly supports." *Id*. at 16,310. If anything, then, the statement accompanying the 1998 Rule seems to weigh in favor of defendants' interpretation, which gives the Secretary the discretion—but does not impose an obligation—to refer proposed allocation policies to the Advisory Committee and publish them in the Federal Register.

What, then, of the 1999 amendments? Plaintiffs contend that increased oversight of OPTN policies was a primary motivation behind the new version of

the Final Rule, and to be sure, there's evidence for that proposition in HHS's statement accompanying the amended rule. *See, e.g.*, 64 Fed. Reg. 56,656. The statement notes, for example, that HHS decided to establish "an independent scientific review board"—the Advisory Committee on Organ Transplantation—in order to "help [e]nsure that policies and procedures are evidence-based and guided by the best available scientific and medical precepts." *Id.* at 56,652. And, the statement continues, HHS amended § 121.4(b)(2) so that the Committee could "fulfill this . . . responsibility." *Id.* According to plaintiffs, these statements prove that HHS intended the new Advisory Committee to have a broad role in policy development.

But if you keep reading, HHS's statement makes it clear that, even with the 1999 revisions, the Secretary's discretion remains largely intact—the Secretary is only *required* to consult the Advisory Committee in a few circumstances. When HHS's statement refers to Secretarial review of "recommend[ed] to be enforceable" policies—which, again, the new liver-allocation policy is not—it uses mandatory language that mirrors that in § 121.4(b)(2)'s promulgated text: "When the OPTN proposes enforceable policies, the Secretary *will* ask the Committee for its views on the proposals when the proposals are published in the Federal Register for public comment." *Id.* (emphasis added). Contrast that with HHS's statement regarding Secretarial review of "other" policies, which, again, tracks the enacted

text: "A similar approach *may* also be used *should* the Secretary review other OPTN policies." *Id.* (emphasis added). Once again, Secretarial discretion looms large.

In the end, the regulatory history is—at best—a mixed bag for plaintiffs. There is, as plaintiffs point out, language in the 1998 and 1999 HHS statements that speaks generally about the importance of oversight of OPTN policies. But there is also language consistently recognizing that the Secretary has broad discretion when it comes to the review of non-"recommend[ed] to be enforceable" OPTN policies, like the liver-allocation policy at issue here.[11]

* * *

In the end, to the extent they are discernible, § 121.4(b)(2)'s "purpose" and "history" provide no basis for second-guessing—let alone countermanding—what its text and structure clearly indicate.

[11] To the extent it matters, the post-enactment regulatory history is decidedly *not* a mixed bag, but rather stands squarely against plaintiffs' interpretation of § 121.4(b)(2). In the nearly 20 years since the current version of the Final Rule was published, not a single organ-allocation policy has ever been referred to the Advisory Committee or published in the Federal Register. For all the opacity of HHS's 1998 and 1999 statements, then, its actions since have been clear, and they provide at least some evidence that HHS did not intend to subject non-enforceable organ-allocation policies to § 121.4(b)(2)'s enhanced review procedures. *Cf. Kisor*, 139 S. Ct. at 2426 (Gorsuch, J., concurring in the judgment) ("[T]he 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.").

3

There's one last interpretive issue for us to tackle. Plaintiffs contend that defendants' reading of § 121.4(b)(2) violates federal contracting law. In particular, plaintiffs point to the Federal Activities Inventory Reform (FAIR) Act, Pub. L. No. 105-270, 112 Stat. 2382 (1998), and the Federal Acquisition Regulation, 48 C.F.R. 7.503, which they say together embody a rule that "[c]ontracts shall not be used for the performance of inherently governmental functions." Appellants' Br. at 37–38. Plaintiffs assert that defendants' interpretation of § 121.4(b)(2) would "allow[] [United Network] to perform the inherently governmental function of determining a policy's consistency with federal law." *Id*. at 38. Plaintiffs' argument, as we understand it, is not that United Network violates the FAIR Act and the FAR regulation simply by developing and proposing new organ-allocation policies, but rather that if defendants' interpretation of § 121.4(b)(2) is adopted, United Network (as the OPTN) would be given a new task—assessing whether its policies are consistent with federal law—which would violate the FAIR Act and the FAR regulation.[12] We don't see it that way, for two reasons.

First, it's not clear why the OPTN would have an affirmative obligation to ensure its policies' compliance with federal law under one reading of

[12] Although we reject plaintiffs' FAIR- and FAR-related argument on other grounds, it's worth noting at the outset that the FAIR Act, in particular, appears to be totally irrelevant to plaintiffs' claim. The FAIR Act does not, as plaintiffs repeatedly suggest, prohibit the use of contracts for

§ 121.4(b)(2), but not another. The specific provision of § 121.4(b)(2) at issue prescribes the Secretary's duties, not the OPTN's. We don't think that interpreting the Secretary's duties in a way that does not require referral of the new liver-allocation policy to the Advisory Committee or its publication in the Federal Register would necessarily expand the OPTN's responsibilities, as plaintiffs' argument seems to suggest.

Second, even under defendants' more constrained reading of § 121.4(b)(2), the OPTN cannot unilaterally evade all Secretarial oversight. The Secretary maintains significant authority to review OPTN's proposed policies. As defendants point out—and as the regulation's plain text makes clear—the Secretary can always "direct" OPTN's Board of Directors to provide him with a proposed policy 60 days in advance of its implementation, thereby bringing it within § 121.4(b)(2)'s ambit. Or, wholly separately, under § 121.4(d) the Secretary can review and suggest revision to any OPTN policy that has been the subject of a critical comment. Indeed, that's exactly what happened here; it was pursuant to the Secretary's § 121.4(d) authority that HHS decided that the current

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the performance of inherently governmental functions. In fact, plaintiffs' argument seems to rest on an understanding of the FAIR Act that is 180° wrong. The FAIR Act is a reporting statute that requires federal agencies to annually publish lists of activities that are performed by *government employees* (not private contractors) and are *not* (rather than are) inherently governmental functions. *See* 112 Stat. 2382 (1998).

liver-allocation policy—the one that plaintiffs favor—"cannot be justified" under the Final Rule and must be replaced.

Contrary to plaintiffs' suggestions, therefore, defendants' interpretation of § 121.4(b)(2) does not give the OPTN—here, United Network—free reign over the country's organ-allocation policy. The Secretary maintains important—and significant—oversight over the process, as the facts of this case themselves demonstrate.

* * *

The bottom line: Defendants' interpretation of § 121.4(b) clearly makes the most sense of the regulation's text and structure, and none of the remaining tools of construction remotely displace that conclusion. We are confident, therefore—even without resorting to principles of agency deference—that defendants' interpretation should prevail. Accordingly, we hold that the district court did not err in concluding that plaintiffs failed to demonstrate a substantial likelihood of success on the merits of their claim that the Secretary neglected to follow legally required procedures during the new liver-allocation policy's development.[13]

[13] Because we hold that the district court correctly concluded that plaintiffs had failed to demonstrate a substantial likelihood of success, we need not consider whether the remaining factors weigh in favor of a preliminary injunction. *See GeorgiaCarry.Org, Inc. v. U.S. Army Corps of Eng'rs*, 788 F.3d 1318, 1329 (11th Cir. 2015) ("Because the plaintiffs have not shown a substantial likelihood of success on the merits, we need not consider the remaining factors in the preliminary injunction test."); *ACLU of Fla., Inc. v. Miami-Dade Cty. Sch. Bd.*, 557 F.3d 1177, 1198 (11th Cir. 2009) ("Failure to show any of the four factors [of the preliminary injunction

B

What of plaintiffs' remaining claims? In its order denying plaintiffs' motion for temporary injunctive relief, the district court didn't address plaintiffs' alternative contentions that HHS's and United Network's actions in adopting the new liver-allocation policy (1) were both arbitrary and capricious and (2) violated the Fifth Amendment's Due Process Clause. We are wary of diving head-first into claims that the district court hasn't yet considered, and we are especially wary of doing so with respect to *these* claims—both of which will likely turn on fact- and context-intensive questions that the district court is better equipped to decide in the first instance.

Plaintiffs' arbitrary-and-capricious claim, for instance, depends in part on the premise that United Network constitutes an "agency" within the meaning of the APA. 5 U.S.C. § 701(b)(1). And that question—which, so far as we can tell, has yet to be addressed by any federal court—turns on whether United Network exercises "substantial independent [government] authority." *Dong v. Smithsonian Inst.*, 125 F.3d 877, 881 (D.C. Cir. 1997). Similarly, for plaintiffs to have a cognizable due process claim against United Network, its actions in adopting the new policy must be considered "state action"—a question that turns on whether

test] is fatal, and the most common failure is not showing a substantial likelihood of success on the merits.").

United Network's conduct "resulted from the exercise of a right or privilege having its source in state authority" and whether United Network can "be described in all fairness as a state actor." *Edmonson v. Leesville Concrete Co.*, 500 U.S. 614, 620 (1991) (citation omitted).

And beyond those threshold issues, more fact-dependent questions await. For plaintiffs' arbitrary-and-capricious claim: Was HHS's decision to direct the new policy's development based on sufficient evidence? Did United Network use the appropriate procedures in considering the new policy? Did it adequately consider public comments? What role, if any, did the expedited timeline play? Does the new policy substantively comply with statutory and regulatory requirements? And for plaintiffs' due process claim: Do plaintiffs have a life, liberty, or property interest that has been affected by the new policy? If so, did United Network's policies adequately afford them an opportunity to be heard? Did HHS's?

We think that these questions, which are unavoidably fact-sensitive, should be addressed first by the district court. *See Access Now, Inc. v. Southwest Airlines Co.*, 385 F.3d 1324, 1331 (11th Cir. 2004) (noting that this Court is particularly hesitant to address "fact-bound issues" not considered by the district court). We are, after all, a court of review, not a court of first view. *See, e.g.*, *Bartholomew v.*

AGL Res., Inc., 361 F.3d 1333, 1341 n.5 (11th Cir. 2004). We therefore remand plaintiffs' remaining claims to the district court for its consideration.

III

For the foregoing reasons, we hold that plaintiffs have not shown a substantial likelihood of success on the merits of their first claim—their allegation that the Secretary failed to follow legally required procedures under 42 C.F.R. § 121.4(b) during the new liver-allocation policy's development. We also hold, however, that the district court should decide plaintiffs' remaining claims—their APA-based arbitrary-and-capricious claim and their Fifth Amendment Due Process claim—in the first instance. Accordingly, the district court's order denying plaintiffs' motion for a temporary restraining order is **AFFIRMED** in part and **REMANDED** in part.