

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

AMERICAN MEDICAL ASSOCIATION,)
AMERICAN HOSPITAL ASSOCIATION,)
RENOWN HEALTH, UMASS MEMORIAL)
HEALTH CARE, INC., STUART S.)
SQUIRES, M.D., and VICTOR F. KUBIT,)
M.D.,)

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF)
HEALTH AND HUMAN SERVICES,)
DEPARTMENT OF LABOR,)
DEPARTMENT OF THE TREASURY,)
OFFICE OF PERSONNEL MANAGEMENT,)
and the CURRENT HEADS OF THOSE)
AGENCIES IN THEIR OFFICIAL)
CAPACITIES,)

Defendants.

Case No.: 1:21-cv-03231

**MOTION OF THE COLLEGE OF AMERICAN PATHOLOGISTS
FOR LEAVE TO FILE AN *AMICUS CURIAE* BRIEF IN SUPPORT OF PLAINTIFFS**

Jaime L.M. Jones (*pro hac vice forthcoming*)
jaime.jones@sidley.com
Joseph R. LoCascio (*pro hac vice forthcoming*)
joseph.locascio@sidley.com
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, Illinois 60603
Tel: (312) 853-0751
Fax: (312) 853-7036

Eric D. McArthur (D.C. Bar No. 987560)
emcarthur@sidley.com
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Tel: (202) 736-8018
Fax: (202) 736-8711

Counsel for the College of American Pathologists

Pursuant to this Court's Civil Local Rule ("LCvR") 7(o), the College of American Pathologists (the "CAP") respectfully moves for leave to file a brief as *amicus curiae* in the above-captioned case in support of Plaintiffs' Motion for Stay Pending Judicial Review, or in the Alternative, for Summary Judgment. The proposed *amicus* brief is attached hereto as Exhibit A. Plaintiffs have consented to the filing of this brief. Defendants take no position.

District courts have "broad discretion" to permit *amicus* participation. *Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs*, 519 F. Supp. 2d 89, 93 (D.D.C. 2007). *Amicus* participation is appropriate where "the *amicus* has unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide," *Jin v. Ministry of State Sec.*, 557 F. Supp. 2d 131, 137 (D.D.C. 2008) (quoting *Ryan v. Commodity Futures Trading Comm'n*, 125 F.3d 1062, 1063 (7th Cir. 1997)), or where the *amicus* has "relevant expertise and a stated concern for the issues at stake in [the] case," *District of Columbia v. Potomac Elec. Power Co.*, 826 F. Supp. 2d 227, 237 (D.D.C. 2011). *See also Ellsworth Assocs., Inc. v. United States*, 917 F. Supp. 841, 846 (D.D.C. 1996) (allowing non-party with special interest in and knowledge of issues to participate as *amicus curiae*); *Priests for Life v. Dep't of Health & Hum. Servs.*, No. 1:13-cv-01261-EGS (D.D.C. Oct. 25, 2013); *Jin*, 557 F. Supp. 2d at 137–38.

The CAP has both a strong interest in the matter before the Court and a unique perspective that it believes would assist the Court and that the Court would not otherwise obtain from the parties. The CAP is the nation's largest organization of board-certified pathologists and the leading provider of laboratory accreditation and proficiency testing programs. Offering the experiences of healthcare providers who specialize in the diagnosis of diseases in the lab setting, the CAP has deep expertise in how pathologists are affected by the No Surprises Act ("NSA"). The CAP has almost 18,000 members practicing across the country in nearly every medical subspecialty. The

CAP's members will provide out-of-network services governed by the NSA, and their reimbursement for those services will be determined through the IDR process at issue in this case.

Indeed, the CAP worked closely with Congress and other stakeholders in the development of the NSA.¹ The CAP provided initial recommendations to the Department of Health and Human Services in June 2021.² In September 2021, the CAP submitted comments on the first rule implementing aspects of the NSA, "Requirements Related to Surprise Billing; Part I," 86 Fed. Reg. 36,872 (July 13, 2021).³ And in December 2021, the CAP submitted comments on the rule at issue here, "Requirements Related to Surprise Billing; Part II," 86 Fed. Reg. 55,980 (Oct. 7, 2021).⁴

Leveraging the CAP's experience working on the NSA and its implementing regulations, the proposed *amicus* brief supplements the information provided by the parties on the IDR process. In addition to providing textual arguments complementing those provided in Plaintiffs' briefing as to why Defendants' presumption in favor of the qualifying payment amount ("QPA") is unlawful, the proposed *amicus* brief provides broader context around how Defendants have structured the IDR process to make it virtually certain that IDR entities will select the bid closest to the QPA as the out-of-network reimbursement rate, and how pathologists and their patients will be harmed by this regime because the QPA is often below fair market value reimbursement. The information the CAP can provide regarding how Defendants have warped the IDR process to channel out-of-network reimbursement to an unfair benchmark that will harm pathologists and their patients is

¹ Letter from Coll. of Am. Pathologists to Xavier Becerra, Sec'y, Dep't of Health & Hum. Servs. (June 21, 2021), <https://documents.cap.org/documents/CAP-Recommendations-No-Surprises-Act-Regulations.pdf>.

² *Id.*

³ Coll. of Am. Pathologists, Comment Letter on "Requirements Related to Surprise Billing; Part I" (Sept. 7, 2021), <https://www.regulations.gov/comment/CMS-2021-0117-7439>.

⁴ Coll. of Am. Pathologists, Comment Letter on "Requirements Related to Surprise Billing; Part II" (Dec. 6, 2021), <https://www.regulations.gov/comment/CMS-2021-0156-5229>.

plainly “relevant to the disposition of the case.” LCvR 7(o)(2); *see also Neonatology Assocs., P.A. v. Comm’r*, 293 F.3d 128, 132 (3d Cir. 2002) (Alito, J.) (“Even when a party is very well represented, an amicus may provide important assistance to the court,” such as by “explain[ing] the impact a potential holding might have on an industry or other group.”) (quoting Luther T. Munford, *When Does the Curiae Need An Amicus?*, 1 J. APP. PRAC. & PROCESS 279 (1999))).

The CAP’s *amicus* brief also is “timely.” LCvR 7(o)(2). Plaintiffs initiated this litigation just two weeks ago, on December 9, 2021, and under the briefing scheduling set by the Court, Defendants’ response to Plaintiffs’ motion is not due until January 24, 2022, affording Defendants an entire month to respond to the *amicus* brief. Defendants will suffer no prejudice, and the CAP’s *amicus* brief will not delay—let alone “unduly delay,” LCvR 7(o)(2)—the Court’s consideration of the Plaintiffs’ motion. *Cf. Pratt v. Indian River Cent. Sch. Dist.*, No. 7:09-CV-0411, 2010 WL 11681606, at *4 (N.D.N.Y. Dec. 6, 2010) (motion for leave to participate as *amicus* was not too late, because it was filed before the court had rendered a decision on the relevant motion).

For these reasons, the CAP respectfully requests that the Court grant its motion for leave to file the proposed *amicus* brief.

Dated: December 23, 2021

Respectfully submitted,

/s/ Eric D. McArthur

Eric D. McArthur (D.C. Bar No. 987560)

emcarthur@sidley.com

SIDLEY AUSTIN LLP

1501 K Street, N.W.

Washington, D.C. 20005

Tel: (202) 736-8018

Fax: (202) 736-8711

Jaime L.M. Jones (*pro hac vice forthcoming*)

jaime.jones@sidley.com

Joseph R. LoCascio (*pro hac vice forthcoming*)

joseph.locascio@sidley.com

SIDLEY AUSTIN LLP

One South Dearborn

Chicago, Illinois 60603

Tel: (312) 853-0751

Fax: (312) 853-7036

*Counsel for the College of American
Pathologists*

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States District Court for the District of Columbia by using the court's CM/ECF system on December 23, 2021. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the court's CM/ECF system.

Dated: December 23, 2021

/s/ Eric D. McArthur

Eric D. McArthur (D.C. Bar No. 987560)

emcarthur@sidley.com

SIDLEY AUSTIN LLP

1501 K Street, N.W.

Washington, D.C. 20005

Tel: (202) 736-8018

Fax: (202) 736-8711

EXHIBIT A

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UNITED STATES DEPARTMENT OF)
HEALTH AND HUMAN SERVICES, DE-)
PARTMENT OF LABOR, DEPARTMENT)
OF THE TREASURY, OFFICE OF PER-)
SONNEL MANAGEMENT, and the CUR-)
RENT HEADS OF THOSE AGENCIES IN)
THEIR OFFICIAL CAPACITIES,)

Defendants.

Case No.: 1:21-cv-03231

**BRIEF OF THE COLLEGE OF AMERICAN PATHOLOGISTS AS *AMICUS CURIAE*
IN SUPPORT OF PLAINTIFFS' MOTION FOR STAY OR SUMMARY JUDGMENT**

Jaime L.M. Jones (*pro hac vice forthcoming*)
jaime.jones@sidley.com
Joseph R. LoCascio (*pro hac vice forthcoming*)
joseph.locascio@sidley.com
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, Illinois 60603
Tel: (312) 853-0751
Fax: (312) 853-7036

Eric D. McArthur (D.C. Bar No. 987560)
emcarthur@sidley.com
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Tel: (202) 736-8018
Fax: (202) 736-8711

Counsel for the College of American Pathologists

STATEMENT OF COUNSEL

No party's counsel authored this brief in whole or in part; no party or party's counsel contributed money intended to fund the preparation or the submission of this brief; and no person other than the *amicus curiae*, its members, and its counsel contributed money intended to fund the preparation or the submission of this brief.

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INTERESTS OF *AMICUS CURIAE*

The College of American Pathologists (“CAP”) is both the world’s largest organization of board-certified pathologists and the leading provider of laboratory accreditation and proficiency testing programs. Formed in 1946, the CAP has since grown to almost 18,000 members. The CAP serves patients and its members by fostering and advocating for excellence in the practice of pathology and laboratory medicine around the world. As medicine, technology and pathology have evolved since 1946, the CAP has led the way to meet new challenges that result in better patient outcomes. Because pathologists are closely involved in most aspects of patient care by providing anatomic and clinical services, they are valuable consultants to primary care physicians and specialists. For example, thousands of women each day rely on a pathologist’s interpretation of routine testing such as Pap smears to determine if cancerous cells exist. Pathologists have already helped millions of women with breast cancer by developing faster and better ways to analyze their molecular makeup and prescribe treatment plans tailored to their unique form of the disease. Better-targeted testing translates into better treatment plans for patients as medical oncology teams avoid wasting time and expense administering costly therapies that may not prove effective. In narrowing the focus of diagnosis in this way, pathologists do more than ensure patients receive the right test at the right time: they also protect patients and the health care system against inappropriate requests for an increasingly complex and expensive array of diagnostic testing.

The CAP has an acute interest in this case because its members will provide services governed by the No Surprises Act (“NSA”), and their reimbursement for those services will be determined through the independent dispute resolution (“IDR”) process at issue in this case. The CAP is intimately involved in addressing coverage and reimbursement issues facing pathologists in the legislative and regulatory landscape. The CAP has worked closely with the government and

stakeholders on the implementation of the NSA, including by submitting comments on two interim final rules implementing various aspects of the law.¹ *See Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021) (“July Rule”); *Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021) (“September Rule”).

Through its advocacy efforts around the NSA, the CAP has consistently worked to safeguard patients from surprise medical bills and advocated for an IDR process that both keeps patients out of the middle of billing disputes and ensures fair reimbursement for out-of-network services. However, while the IDR process as implemented by the Departments does successfully take patients out of billing disputes, it does not ensure fair reimbursement for providers of out-of-network services. By requiring IDR entities to presume that the artificially deflated qualifying payment amount (“QPA”) is an appropriate reimbursement amount, the September Rule contravenes both the terms of the statute and congressional intent, and will result in inadequate reimbursement for healthcare providers, including the CAP’s members, which in turn will harm patients as they lose access to pathologists and other physicians.

Accordingly, the CAP respectfully urges the Court to vacate the provisions of the September Rule that unlawfully require IDR entities to employ a presumption in favor of the QPA.

INTRODUCTION

In the NSA, Congress carefully crafted a balanced IDR process to resolve disputes between healthcare providers and insurers over reimbursement for out-of-network services. As part of that

¹ *See* Letter from CAP to Xavier Becerra, Sec’y, Dep’t of Health & Hum. Servs. (June 21, 2021), <https://documents.cap.org/documents/CAP-Recommendations-No-Surprises-Act-Regultions.pdf>; CAP, Comment Letter on “Requirements Related to Surprise Billing; Part I” (Sept. 7, 2021), <https://www.regulations.gov/comment/CMS-2021-0117-7439>; CAP, Comment Letter on “Requirements Related to Surprise Billing; Part II” (Dec. 6, 2021), <https://www.regulations.gov/comment/CMS-2021-0156-5229>.

process, Congress directed IDR entities, in every case, to consider a detailed list of factors enumerated in the statute in order to determine which party's offer best reflects the value of the items or services at issue. In so doing, Congress rejected approaches that would have tied healthcare provider reimbursement to the QPA, opting instead for a process in which an independent, expert arbitrator would consider all the relevant facts and circumstances in a particular case.

In the September Rule, however, the Departments nullified the balance Congress struck. Under the guise of "interpretation," the Departments rewrote the statute to require IDR entities to give presumptive weight to the QPA, sharply limiting their ability to consider the additional statutory factors and transforming the process from one that Congress designed to be "independent" to one that will systematically advantage insurers and undercompensate physicians. This foray into administrative legislation is manifestly unlawful. If Congress had intended the QPA to be given presumptive effect in the IDR process, it would have said so. No principle of statutory interpretation allows the Departments to add material terms to the statute or to circumscribe the discretion Congress granted to IDR entities to weigh the statutory factors as they deem best.

The Departments' presumption in favor of the QPA in the IDR process is especially pernicious because the QPA will often understate the true value of healthcare providers' services as reflected by rates paid in the commercial marketplace. In an effort to minimize patient cost-sharing, the Departments in the July Rule made a series of decisions that both deflate QPAs and prevent healthcare providers from having meaningful insight into how insurers calculate them. Especially in light of those decisions, it is essential that IDR entities be free to consider the full range of statutory factors Congress directed them to consider in determining healthcare provider reimbursement, without an administratively manufactured thumb on the scales in favor of the QPA.

If not set aside, the Departments’ unlawful presumption in favor of the QPA will cause substantial harm. The leverage the presumption gives to insurers will allow them to drive down both in-network and out-of-network reimbursement and force more healthcare providers out-of-network. This will require healthcare providers to cut back on services and will likely result in the closure of some practices. The ultimate losers will be patients, who will have less access to care and suffer worse health outcomes, contrary to Congress’s intent in the NSA.

ARGUMENT

I. Under the Guise of “Interpretation,” the Departments Improperly Added to the Statute a Material Term That Conflicts With Congress’s Balanced Design.

In requiring IDR entities to treat the QPA as the presumptive benchmark, the Departments claimed to be “interpret[ing]” the statute. 86 Fed. Reg. at 55,996. They did not, however, identify any statutory term or phrase that could be “interpreted” to make the offer closest to the QPA presumptively controlling. That is because there is none. The statute requires only that the IDR entity “shall consider” and “tak[e] into account” the QPA and the other factors enumerated in the statute, without prioritizing the QPA or subordinating the other factors to it in any way. The Departments’ “interpretation” thus violates the “fundamental principle of statutory interpretation that absent provisions cannot be supplied by the courts”—or by administrative agencies. *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2381 (2020) (cleaned up).

That principle has particular force here, for at least four reasons. *First*, Congress addressed the IDR process in painstaking and exhaustive detail. In addition to specifying such minutiae as, for example, the timeline for each step of the process, Congress spelled out with care the precise factors that IDR entities “shall” and “shall not” consider “[i]n determining which offer is the payment to be applied,” 42 U.S.C. § 300gg-111(c)(5)(C)–(D). Congress required IDR entities to consider *each* factor in *every* case. Congress nowhere specified that the QPA was “more equal” than

the other factors or should be given presumptive weight in the decisional process. Especially in a statute as prescriptive as this one, it is “highly improbable” that Congress intended for the QPA to be given presumptive weight, but “absentmindedly forgot to mention” it. *Transamerica Mortg. Advisors, Inc. v. Lewis*, 444 U.S. 11, 20 (1979) (internal quotation marks omitted).

Second, “[a]textual judicial”—or administrative—“supplementation is particularly inappropriate when, as here, Congress has shown that it knows how to adopt the omitted language or provision.” *Rotkiske v. Klemm*, 140 S. Ct. 355, 361 (2019). Congress knows how to impose a “rebuttable presumption” when it wants to; it has done so in many statutes.² Indeed, elsewhere in the Consolidated Appropriations Act, 2021 itself—the same enactment that included the NSA—Congress imposed a “rebuttable presumption.”³ Had Congress intended to create a “rebuttable presumption” in favor of the QPA, it could easily have written the statute to say so. It did not, and the Departments may not add provisions that Congress omitted. *See Alabama v. North Carolina*, 560 U.S. 330, 352 (2010) (“We do not—we cannot—add provisions to a federal statute.”).

Third, a presumption in favor of the QPA is not a minor gloss on the IDR process as set forth in the statute, but rather a fundamental restructuring that transforms the balanced process

² *See, e.g.*, 8 U.S.C. § 1158(b)(1)(B)(iii) (creating a “rebuttable presumption” of credibility); 15 U.S.C. § 3608(b) (creating a “rebuttable presumption” of unconscionability); 16 U.S.C. § 5509(e) (creating a “rebuttable presumption” of a statutory violation); 18 U.S.C. § 1388(e) (creating a “rebuttable presumption” of willfulness); *id.* § 1469(a) (creating a “rebuttable presumption” of movement in interstate commerce); 21 U.S.C. § 853(d) (creating a “rebuttable presumption” of forfeiture); 30 U.S.C. § 1466(e) (creating a “rebuttable presumption” of a statutory violation); 39 U.S.C. § 3008(f) (creating a “rebuttable presumption” of mailing after a specified date); *id.* § 3653(e) (creating a “rebuttable presumption” of statutory compliance); 42 U.S.C. § 667(b)(2) (creating a “rebuttable presumption” of correctness of child support calculated according to guidelines); *id.* § 15942(a) (creating a “rebuttable presumption” of exemption from environmental review).

³ Trademark Modernization Act of 2020, Pub. L. No. 116-260, div. Q, tit. II, subtit. B, 134 Stat. 1182, 2200–10, 2208 (codified at 15 U.S.C. § 1116(a)) (“Rebuttable Presumption of Irreparable Harm”) (“A plaintiff seeking any such injunction shall be entitled to a rebuttable presumption of irreparable harm upon a finding of a violation identified in this subsection . . .”).

Congress created into a rubber stamp. Under the statute as written, IDR entities must consider *all* the factors, without any presumptions, and select the offer that, in the IDR entity’s judgment, best represents the value of the items or services. The Departments’ presumption robs IDR entities of their “independence” and instead compels them to select the bid closest to the QPA. The statute cannot be read to impose such a transformative requirement *sub silentio*. “Congress . . . does not . . . hide elephants in mouseholes.” *Whitman v. Am. Trucking Ass ’ns*, 531 U.S. 457, 468 (2001). Nor can major new requirements be found lurking in between the statutory lines or in “implications from ‘penumbra[s]’ [and] ‘emanations’” from provisions that do not speak to the issue at hand. Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 97 (2012).

Fourth, Congress considered bills that would have made the QPA the benchmark reimbursement rate. *See, e.g.*, Ban Surprise Billing Act, H.R. 5800, 116th Cong. § 2(a) (2020); Lower Health Care Costs Act, S. 1895, 116th Cong. § 103(a) (2019); No Surprises Act, H.R. 3630, 116th Cong. § 2(a) (2019). But Congress rejected those bills in favor of “an IDR process overseen by an independent and neutral arbiter who must consider a number of factors *equally* in deciding whether to select the provider or [insurer]’s offer.” Letter from Richard E. Neal, Chairman, and Kevin Brady, Ranking Member, U.S. House of Representatives Comm. on Ways & Means, to Xavier Becerra, Sec’y, U.S. Dep’t of Health & Hum. Servs., Martin Walsh, Sec’y, U.S. Dep’t of Lab., and Janet Yellen, Sec’y, U.S. Dep’t of Treasury (Oct. 4, 2021) (emphasis added). “Congress deliberately crafted the law to avoid any one factor tipping the scales during the IDR process.” *Id.* Indeed, a recent letter from more than 150 Members of Congress explained that the September Rule’s benchmark approach “do[es] not reflect the way the law was written, [and] do[es] not reflect a policy that could have passed Congress.” Letter from 152 Members of U.S. House of

Representatives to Xavier Becerra, Sec’y, U.S. Dep’t of Health & Hum. Servs., Martin Walsh, Sec’y, U.S. Dep’t of Lab., and Janet Yellen, Sec’y, U.S. Dep’t of Treasury (Nov. 5, 2021).⁴

At bottom, “Congress could have limited [IDR entities’] discretion in any number of ways,” including by imposing a presumption in favor of the QPA, “but it chose not to do so.” *Little Sisters*, 140 S. Ct. at 2380. The Departments are not at liberty to countermand that decision, under the guise of “interpretation” or otherwise. By “adding terms not found in the statute,” and “imposing limits on [IDR entities’] discretion that are not supported by the text,” the Departments “alter[ed], rather than . . . interpret[ed]” the statute. *Id.* at 2381.

II. Making the QPA the Presumptive Benchmark for Healthcare Provider Reimbursement Will Harm Both Providers and Patients.

Warping the IDR process from an independent inquiry into one that is presumptively controlled by the QPA not only is facially unlawful, but also will lead to a host of harmful effects on pathologists and their patients. The Departments’ implementation of the NSA has significantly weakened the incentives for insurance companies to pay in-network rates above the QPA, which is particularly problematic in light of the many flaws relating to how the Departments have authorized insurance companies to calculate QPAs. The result will be rate reductions that will force providers out of the market, contract terminations, and reduced access to pathologists.

The presumption in favor of the QPA is only one of the ways in which the Departments structured the IDR process to ensure that IDR entities virtually always select the bid closest to the QPA, rather than genuinely weighing the statutory factors and reaching an “independent” decision. These other decisions about how to structure the IDR process highlight how the Departments have made the QPA a de facto benchmark for healthcare provider reimbursement, in clear contravention of the independent, totality-of-the-circumstances inquiry Congress mandated.

⁴ https://wenstrup.house.gov/uploadedfiles/2021.11.05_no_surprises_act_letter.pdf.

For example, the fee structure the Departments created discourages IDR entities from undertaking a thorough inquiry. IDR entities will generally receive a flat rate payment of \$200–\$500 for adjudicating single claims and \$268–\$670 for reviewing batched claims. Ctrs. for Medicare & Medicaid Servs., Technical Guidance No. 2021-01, *Calendar Year 2022 Fee Guidance for the Federal Independent Dispute Resolution Process Under the No Surprises Act* (Sept. 30, 2021).⁵ This compensation is below the rate that arbitrators receive for engaging in an independent inquiry under similar state IDR processes. *See id.* While these fees may cover the work necessary to reflexively select the offer closest to the QPA, they will often be inadequate to compensate IDR entities for the work necessary to reach a reasoned decision after balancing the multiple factors Congress required them to consider in the NSA. This is particularly true for batched claims, which may require review of dozens of claims involving the same billing code but with important claim-by-claim differences relevant to the appropriate reimbursement rate for each. For example, pathologists face different costs and resources in different settings, especially as between hospital laboratories and freestanding labs. Such nuances must be taken into account to reach fair and reasonable reimbursement rates, and Congress required IDR entities to consider them.

Compounding this problem, if the IDR entity does select the offer farther from the QPA, it must draft “a detailed explanation” justifying its decision. 86 Fed. Reg. at 56,000. That justification must describe “the additional considerations relied upon, whether the information about those considerations submitted by the parties was credible, and the basis upon which the certified IDR entity determined that the credible information demonstrated that the QPA is materially different from the appropriate out-of-network rate.” *Id.* No such justification is required of the IDR entity if it

⁵ <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Technical-Guidance-CY2022-Fee-Guidance-Federal-Independent-Dispute-Resolution-Process-NSA.pdf>.

chooses the bid closest to the QPA. By imposing this additional work if the IDR entity dares to select the offer farther from the QPA, the Departments have structured the process to disincentivize IDR entities from overcoming the unlawful presumption imposed on them.

The Departments thus have done everything within their power—and beyond their power—to structure the IDR process to drive provider reimbursement to the QPA. This is problematic not only because benchmark rate-setting conflicts with the nuanced system Congress created in the NSA, under which reimbursement decisions are supposed to be made based on all the facts and circumstances of a given case, but also because the QPA as implemented by the Departments is not a good proxy for the average contracted rate *as paid in the market*.

The NSA defines the QPA as “the median of the contracted rates recognized by the plan or issuer” for the same or similar item or service furnished by the provider in the same or similar specialty and in the same geographic region. 42 U.S.C. § 300gg-111(a)(3)(E). The Departments interpreted the “median contracted rate” to mean that “each contracted rate for a given item or service [is] treated as a single data point when calculating a median contracted rate.” 86 Fed. Reg. at 36,889. Setting aside whether this interpretation is permissible, a series of other choices by the Departments have driven down the median contracted rate.

For example, the statute does not impose a minimum on the number of times a contracted rate must be used in order to be counted as a contracted rate for purposes of calculating the QPA. But the Departments created one, just as they created a rebuttable presumption in favor of the QPA in the IDR process. According to the Departments, “solely for purposes of the definition of contracted rate, a single case agreement, letter of agreement, or other similar arrangement between a plan or issuer and a provider, facility, or provider of air ambulance services does not constitute a contract, and the rate paid under such an agreement should not be counted among the plan’s or

issuer's contracted rates." *Id.* Single case agreements reflect a contracted rate for a service, negotiated at arm's length between insurers and providers. The Departments' sole explanation for excluding these contracted rates from the definition of "contracted rates" is that the Departments interpret this term to include only rates negotiated to participate in-network, because this interpretation "most closely aligns with the statutory intent of ensuring that the QPA reflects market rates under typical contract negotiations." *Id.* The limitation that "contracted rates" must be for network participation is found nowhere in the statute, and the Departments do not explain why single case agreements do not reflect "market rates under typical contract negotiations." In the experience of the CAP's members, single case agreements are often higher than the average network contracted rate, and as a result, excluding these rates pushes down the QPA.

While the Departments purported to find within the statutory text an exclusion for contracted rates used only *once*, inexplicably, they permit insurance companies to incorporate into their QPAs contracted rates that *have never been used* and may never be used. The Departments easily could have required that insurance companies actually remit payment under a particular contracted rate in order to use the rate in their QPA calculations, but they have not done so. Giving rates that are never used the same weight as frequently used rates distorts the ability of the QPA to stand as a proxy for "market rates under *typical* contract negotiations."

Because the NSA explicitly tethers patient cost-sharing to the QPA, *see* Compl. ¶ 35, minimizing the QPA means lowering patient out-of-pocket expenses. The Departments have been clear that they made policy choices to reduce patient cost-sharing. *See, e.g.*, 86 Fed. Reg. at 36,891. The CAP fully supports rules that allow for affordable patient cost-sharing. But when the Departments engrafted onto the IDR process a presumption in favor of the QPA, they unlawfully skewed out-of-network provider reimbursement. That is, in the September Rule, the Departments made

the QPA—a metric that has been deflated to lower patient cost-sharing—presumptively controlling for out-of-network provider reimbursement. The Departments have acknowledged that under the NSA, the out-of-network reimbursement rate “generally does not affect the cost-sharing amount the individual must pay.” *Id.* at 36,884. Yet they have created a system in which benchmarks driving patient cost-sharing will not only inform but presumptively dictate the amount providers receive, which is a rate that will often be below fair market value compensation.

Compounding the flaws that make the QPA an inaccurate proxy for reasonable out-of-network reimbursement is the Departments’ decision largely to forgo federal oversight of QPA calculations. Insurers are responsible for calculating QPAs, and the information necessary to do so lies solely within their control. The NSA directs the Departments to “establish through rule-making . . . the information such plan or issuer, respectively, shall share with the nonparticipating provider or nonparticipating facility, as applicable,” about how the plan or issuer “determine[d] the qualifying payment amount.” 42 U.S.C. § 300gg-111(a)(2)(B)(i)–(ii). In the July Rule, the Departments recognized that healthcare providers “subject to the surprise billing rules need transparency regarding how the QPA was determined.” 86 Fed. Reg. at 36,898. They further claimed that they sought “to ensure transparent and meaningful disclosure about the calculation of the QPA while minimizing administrative burdens on plans and issuers.” *Id.* However, the information the Departments require insurance companies to disclose to healthcare providers does not provide any meaningful disclosure about how QPAs are calculated. *See* 45 C.F.R. § 149.140(d)(1).⁶ While

⁶ With each initial payment or denial of payment, plans and issuers must send to providers (1) a statement that the QPA both “applies for purposes of the recognized amount,” and was calculated compliantly; and (2) a statement on how a provider may initiate both the 30-day open negotiation period and the IDR process. 45 C.F.R. § 149.140(d)(1). Further, upon request from providers, plans and issuers must disclose (1) whether the QPA includes “contracted rates that were not on a fee-for-service basis,” and whether the QPA was “determined using underlying fee schedule rates or a derived amount”; (2) information to identify any eligible database used to calculate the median

insurance companies must certify to providers that they have correctly calculated QPAs consistent with the Departments' rules, *id.* § 149.140(d)(1)(ii)(B), providers have absolutely no ability to confirm the veracity of the certifications they receive. Although the NSA encourages the Departments to audit plans and issuers to ensure they are accurately calculating QPAs, and although the NSA gives the Departments audit authority where they lacked pre-existing investigatory powers, *see, e.g.*, 42 U.S.C. § 300gg-111(a)(2)(A), the Departments have made clear that they have little intention of engaging in meaningful auditing, *see* 86 Fed. Reg. at 36,935 (the Department of Health and Human Services “expects to conduct no more than 9 audits annually”).

Moreover, by “[a]nchoring the determination of the out-of-network rate to the QPA,” 86 Fed. Reg. at 55,996, the Departments' unlawful presumption will drive not only *out-of-network* reimbursement to the QPA, it will drive *in-network* reimbursement there as well. That is because, under the September Rule, insurers have the incentive to offer in-network providers rates no higher than the QPA, *i.e.*, no higher than what they can expect to pay if they push providers out-of-network. The Departments have thus incentivized rate cuts, with contract terminations for pathologists unwilling to submit. *See, e.g.*, Letter from 152 House Members, *supra* (explaining how the Departments' approach to the IDR process “could incentivize insurance companies to set artificially low payment rates, which would narrow provider networks and jeopardize patient access to care—the exact opposite of the goal of the law”).

The health insurance industry is a highly consolidated one, and in recent years health insurance companies have increasingly flexed their market power to impose rate cuts on

of the contracted rates; (3) any related service code used to determine the QPA “for an item or service billed under a new service code”; and (4) where applicable, a statement that the insurer's “contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments” “that were excluded for purposes of calculating” the QPA. *Id.* § 149.140(d)(2).

pathologists. The CAP has engaged with insurance companies on behalf of its membership to urge them to revise policies that hinder patient access to pathology services through lack of reasonable payment for those services. Nonetheless, rate reductions have continued to strain pathologists' ability to provide services, particularly in underserved communities.

On top of this dynamic, health insurance companies have increasingly refused to contract with pathologists, even though the CAP's members generally seek out opportunities to be in-network. According to the CAP's annual practice leaders survey, 9% of pathology practice leaders surveyed said that in 2021, they were "denied continued participation in a commercial health plan/insurer network in which [they] were previously a participating provider," and 12% "[a]ttempted to join a commercial health plan/insurer network and [were] denied participating provider status." CAP, *2021 Practice Leader Survey Report* 47 (2021), <https://www.cap.org/advocacy/latest-news-and-practice-data/practice-surveys>. These figures doubled from the CAP's prior survey in 2018, when 4% of pathologists reported being denied continued participation and 6% were denied new participating provider status. CAP, *2018 Practice Leader Survey Report* 47–48 (2018). Health insurers appear poised to take advantage of the NSA to exacerbate these trends. As Plaintiffs noted in their complaint, one insurer "has already threatened to 'terminate agreements' with providers who do not agree to lower rates in light of the new rule." Compl. ¶ 9. More will surely follow if the Department's QPA presumption is allowed to stand.

In sum, the Departments have attempted to compel IDR entities to forgo an independent assessment of appropriate reimbursement rates and instead use the QPA as the de facto benchmark—a figure the Departments have deliberately deflated while also disclaiming any meaningful effort at auditing to ensure accuracy. As a result, healthcare providers will be pushed out of network and/or forced to cut back services. Resulting delays in, or obstacles to, receiving pathology

services could disrupt coordination of care and lead to lower quality outcomes. Pathologists develop and implement methods of molecular analysis that provide for better management of potentially deadly diseases such as cancer. Having access to the right test at the right time can make all the difference in a patient's diagnosis and treatment. A system that drives reimbursement toward a benchmark that is often below fair market value will make it harder for patients to access in-network pathologists and undermine pathologists' ability to continue providing innovative new tests for their patients, contrary to Congress's goals in the NSA.

CONCLUSION

The CAP respectfully urges the Court to set aside the provisions of the September Rule that unlawfully require IDR entities to presume the QPA is the appropriate reimbursement rate.

Dated: December 23, 2021

Respectfully submitted,

/s/ Eric D. McArthur

Eric D. McArthur (D.C. Bar No. 987560)
emcarthur@sidley.com
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Tel: (202) 736-8018
Fax: (202) 736-8711

Jaime L.M. Jones (*pro hac vice forthcoming*)
jaime.jones@sidley.com
Joseph R. LoCascio (*pro hac vice forthcoming*)
joseph.locascio@sidley.com
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, Illinois 60603
Tel: (312) 853-0751
Fax: (312) 853-7036

EXHIBIT B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN MEDICAL ASSOCIATION,)
AMERICAN HOSPITAL ASSOCIATION,)
RENOWN HEALTH, UMASS MEMORIAL)
HEALTH CARE, INC., STUART S.)
SQUIRES, M.D., and VICTOR F. KUBIT,)
M.D.,)

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF)
HEALTH AND HUMAN SERVICES,)
DEPARTMENT OF LABOR,)
DEPARTMENT OF THE TREASURY,)
OFFICE OF PERSONNEL MANAGEMENT,)
and the CURRENT HEADS OF THOSE)
AGENCIES IN THEIR OFFICIAL)
CAPACITIES,)

Defendants.

Case No.: 1:21-cv-03231

[PROPOSED] ORDER

Upon consideration of the College of American Pathologists’ Motion for Leave to File an *Amicus Curiae* Brief, it is hereby ORDERED that the Motion is GRANTED. The Clerk will file the Brief of the College of American Pathologists as *Amicus Curiae* in Support of Plaintiffs’ Motion for Stay or Summary Judgment attached to its motion.

This _____ day of _____, 20__.

Hon. Richard J. Leon
United States District Judge