IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISON

TEXAS HEALTH AND HUMAN SERVICES COMMISSION,

Plaintiff, and

BAYLOR HEALTH CARE SYSTEM, METHODIST HOSPITALS OF DALLAS, and TEXAS HEALTH RESOURCES

Intervenors

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and

XAVIER BECERRA,
Secretary of Health and Human Services,

Defendants.

Civil Action No. 3:19-cv-2857-E

BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION AND TEXAS HOSPITAL ASSOCIATION IN SUPPORT OF PLAINTIFF'S AND INTERVENORS' MOTIONS FOR SUMMARY JUDGMENT

Jordan Campbell
Brown Fox PLLC
8111 Preston Road, Suite 300,
Dallas, Texas 75225
(214) 396-9284
jordan@brownfoxlaw.com

Chad I. Golder (*Pro Hac Vice* Pending)
514 6th Street, NE
Washington, DC 20002
(203) 506-0670
chadgolder@gmail.com

Counsel for Amici Curiae

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INTEREST OF *AMICI CURIAE*[1]

The American Hospital Association (AHA) represents nearly 5,000 hospitals, health systems, and other health care organizations. AHA members are committed to improving the health of the communities they serve and to helping ensure that care is available to and affordable for all Americans. The AHA educates its members on healthcare issues and advocates on their behalf so that their perspectives are considered in formulating health policy. One way in which the AHA promotes the interests of its members is by participating as *amicus curiae* in certain cases.

Founded in 1930, the Texas Hospital Association (THA) is the leadership organization and principal advocate for the state's hospitals and health care systems. One of the largest hospital associations in the country, THA represents more than 85 percent of the state's acute-care hospitals and health care systems, which employ more than 400,000 health care professionals statewide. THA advocates for legislative, regulatory, and judicial means to obtain accessible, cost-effective, high-quality health care for millions of Texas patients.

Amici and their member-hospitals have a direct interest in this case for two principal reasons. *First*, the legal questions at issue here have important consequences for hospitals that participate in the Medicaid program. For nearly 30 years, states have relied on public and private providers to help finance their share of Medicaid program dollars. Those congressionally-approved financial arrangements have helped AHA and THA member-hospitals provide medical care to the 75 million Americans who depend on the Medicaid program as their primary source of health coverage. This court's interpretation of the statutory provision governing "bona fide

[1] In accordance with Federal Rule of Appellate Procedure 29(a)(4)(E), *amici* certify that (1) this brief was authored entirely by counsel for *amici curiae* and not by counsel for any party, in whole or part; (2) no party or counsel for any party contributed money to fund preparing or submitting this brief; and (3) apart from *amici curiae* and their counsel, no other person contributed money to fund preparing or submitting this brief.

provider-related donations" will impact a range of public-private financing arrangements that assist *amici*'s members in treating America's most vulnerable patients.

Second, an important aspect of this case is the history surrounding the Centers for Medicare & Medicaid Services' (CMS) 2019 Medicaid Fiscal Accountability Regulation. Plaintiff, Intervenors, and Defendants discuss this proposed rule in their complaints and summary judgment briefs. *Amici* participated in the rulemaking process for that proposed regulation, offering comment letters that explained why the "net effect" test that is at issue here (and expressly adopted in CMS's proposed rule) was unfairly vague and contrary to the statute it was purportedly clarifying. Critically, CMS withdrew that proposed rule on the basis of comments like *amici*'s. As a participant in this rulemaking process and a frequent participant in many others, *amici* have a strong interest in ensuring that agencies take seriously the words and actions that they choose in notice-and-comment rulemaking processes. That is particularly important when those words and actions make plain, as they do here, that regulated parties did not have fair notice of the relevant legal standards governing them.

INTRODUCTION

"[T]he Medicaid statute ... is designed to advance cooperative federalism." *Wisconsin Dep't of Health and Family Servs. v. Blumer*, 534 U.S. 473, 495 (2002). To accomplish this noble goal, "the federal government assists participating states in funding health care for needy persons." *Sandefur v. Cherry*, 718 F.2d 682, 685 (5th Cir. 1983). The law requires, however, that at least 40% of the state's portion of its Medicaid budget be financed by the state, and up to 60% of the state share may come from local or outside sources. For nearly 30 years, states have relied on private providers to help finance their share of the Medicaid program.

The Department Appeals Board (DAB) decision at issue in this case jeopardizes a significant source of state Medicaid funding. If the DAB's "net effect" test is upheld, the decision

will have perilous consequences for communities across the country. The amount of disallowed funding at issue here—$25 million for a single quarter for only two Texas indigent healthcare public-private collaborative programs—is itself considerable. But the "net effect" test that Defendants seek to impose on states and hospitals would have impacts far beyond one fiscal quarter for a pair of Texas programs. Upholding the DAB's vague and unlawful "net effect" test would cut off state access to important funding streams and introduce substantial uncertainty with respect to how the CMS would evaluate state approaches that are vital to the success of the Medicaid program.

The biggest losers would be the millions of patients who rely on the Medicaid program as their primary source of health coverage. Medicaid patients are "America's poorest and most vulnerable people." Robin Rudowitz, Rachel Garfield, and Elizabeth Hinton, *10 Things to Know about Medicaid: Setting the Facts Straight* (Mar. 6, 2019), https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-setting-the-facts-straight/. They are 83% of America's poor children, 48% of children with special health care needs, and 45% of nonelderly adults with special health care needs (such as physical and developmental disabilities, dementia, and serious mental illness). Medicaid also provides vital care for those suffering from opioid addiction; it provides critical funding for nursing homes; and it pays for nearly half of all childbirths in the average state. *See id*. In most instances, there is no other form of health coverage available for those receiving Medicaid coverage—either because they are too young, too old, or too disabled to work, or because they work in part-time or low-wage jobs that do not offer health care coverage.

The DAB's decision will have particularly dire consequences for poor and vulnerable Texans. Approximately 4 million Texans, the majority of whom are children, rely on Medicaid for their health care. Another 5 million Texans do not have health insurance, which results in

billions of dollars in uncompensated care each year. The Texas health care system relies on provider-related donations, like those at issue here, to offset chronic Medicaid underpayment and uncompensated care. Without these financing mechanisms, the state or local governments would need to increase taxes or divert funds from other priorities to replace the millions of dollars in lost funding.

Shockingly, CMS seeks to impose these massive cuts despite acknowledging in a recent rulemaking process that the law governing "bona fide provider-based donations" was unclear prior to the DAB decision, and that the DAB's "net effect" test may have made those rules even more unclear. This brief describes this rulemaking process and explains why it is so essential to understanding the basic unfairness of what CMS is attempting to do by defending the DAB decision at issue here.

That rulemaking process tells a simple story. Shortly after the DAB issued its decision here, CMS issued a proposed rule in which it admitted that it needed to "clarify" the governing standard for "provider-related donations." Medicaid Fiscal Accountability Regulation, 84 Fed. Reg. 63,722 (Nov. 18, 2019) (hereinafter "Proposed Rule"). To do so, it expressly adopted the DAB's newly-minted "net effect" test. Yet when faced with comment after comment critiquing the "net effect" test as contrary to statute, unlawfully vague, or impermissibly subjecting regulated parties to unfettered agency discretion, CMS withdrew the Proposed Rule. When it did, CMS expressly noted that its withdrawal was "based on the considerable feedback we received through the public comment process." Medicaid Fiscal Accountability Regulation, 86 Fed. Reg. 5,105 (Jan. 19, 2021) (hereinafter "Proposed Rule Withdrawal").

Amici simply ask this Court to take Defendants' words seriously. One way or another, Defendants required Plaintiff and Intervenors to develop their Medicaid financing arrangements

in an unclear legal environment. Based on CMS's own explanation, regulated parties were operating in a legal environment that either required a full dress rulemaking to "clarify" the standard for "bona fide provider-related donations," or the DAB's new "net effect" test was so unclear or unlawful as to warrant a withdrawal of the CMS's proposed codification of that test. Either way, CMS violated basic principles of fairness.

It is blackletter law that a regulatory scheme must be "sufficiently clear to warn a party about what is expected of it." *ExxonMobil Pipeline Co. v. U.S. Dept't of Transp*., 867 F.3d 564, 578 (5th Cir. 2017) (quoting *General Elec. Co. v. E.P.A*., 53 F.3d 1324, 1328–29 (D.C. Cir. 1995)). The notice-and-comment process described in this brief makes plain that CMS knew that the rules for "bona fide provider-related donations" lacked that necessary clarity. Consequently, the disallowance at issue here must be reversed.

ARGUMENT

I. CMS Is Forced To Withdraw A Proposed Rule That Would Have "Clarified" The Definition of "Bona Fide Provider-Related Donations" By Adopting The "Net Effect" Standard That Was Announced For The First Time In The DAB Decision At Issue In This Case

A. CMS Issues a Proposed Rule That Would Have "Clarified" the Definition of "Bona Fide Provider-Related Donations"

In November 2019, CMS issued a proposed rule entitled "Medicaid Fiscal Accountability Regulation." Proposed Rule at Fed. Reg. 63,722. The Proposed Rule addressed "multiple topic areas as part of the overall strategy to improve fiscal integrity." *Id*. One of the many topic areas addressed in the proposed rule was the scope of "bona fide provider-related donations," a statutory term that governs the type of Medicaid financing arrangement at issue in this case. *Id*.

States first began to rely on "provider-related donations" in the mid-1980s. *See id*. at 63,730. Under this financing arrangement, "Medicaid providers would donate funds or agree to be taxed, and the revenue from these taxes and donations would be used to finance a portion of the

state's share of Medicaid expenditures." Congressional Research Service, Medicaid Provider Taxes at 5 (August 5, 2016) (hereinafter "CRS Report"); *see id*. at 63,728 ("The non-federal share may also be funded in part from provider-related donations to the state, but these donations must be 'bona fide' in accordance with section 1903(w) of the Act and implementing regulations."). In many instances, "these arrangements were often designed in such a way as to hold the Medicaid providers harmless for the cost of their taxes or donations." CRS Report at 5. In the early years, some states became increasingly "aggressive" in their use of provider-related donations. That aggressiveness became "a point of contention between the federal government and the states," and Congress was forced to step in. *Id*.

In 1991, Congress enacted the Medicaid Voluntary Contribution and Provider-Specific Tax Amendments (P.L. 102-234), which, among other things, placed certain limitations on the use of provider-related donations to fund a state's portion of its Medicaid bill. It defined "provider-related donations" as "any donation or other voluntary payment (whether in cash or in kind) made (directly or indirectly) to a State or unit of local government by" a health care provider or related entity. 42 U.S.C. § 1396b(w)(1)(A)(i)-(ii). The statute allowed a state to offset federal Medicaid funds only for what it called a "bona fide provider-related donation." 42 U.S.C. § 1396b(w)(1)(B). It defined a "bona fide provider-related donation" as "a provider-related donation that has no direct or indirect relationship (as determined by the Secretary) to payments made under this subchapter to that provider, to providers furnishing the same class of items and services as that provider, or to any related entity, as established by the State to the satisfaction of the Secretary." 42 U.S.C. § 1396b(w)(2)(B); Proposed Rule at 63,730 ("Section 1903(w)(1)(A) of the Act specifies that, for purposes of determining the federal matching funds to be paid to a state, the total amount of the state's Medicaid expenditures must be reduced by the amount of revenue the state collects from

impermissible health care-related taxes and non-bona fide provider-related donations."). Notably, the statute went on to provide that the "Secretary may *by regulation* specify types of provider-related donations described in the previous sentence that will be considered to be bona fide provider-related donations." 42 U.S.C. § 1396b(w)(2)(B) (emphasis added).

By 2019, when CMS issued its proposed Medicaid Fiscal Accountability Regulation, the agency became concerned that some state financing arrangements involving provider-related donations ran afoul of the 1991 Medicaid Voluntary Contribution and Provider-Specific Tax Amendments. *See* Proposed Rule at 63,735 ("[C]ertain states, localities, and private health care providers have designed complex financing structures [that] … appear to violate a variety of requirements in section 1903(w) of the Act and its implementing regulations, which mandate that the state's Medicaid expenditures for which FFP is provided shall be reduced by the sum of any revenues resulting from provider-related donations received by the state during the fiscal year other than bona fide provider-related donations."). To address that asserted concern, the Proposed Rule sought to "clarify" the legal guideposts for the use of provider-related donations. *Id*. at 63,736.

The Proposed Rule's use of the word "clarify" was not accidental. In fact, the Proposed Rule used that term *several times* to explain what it sought to accomplish. For example, the Proposed Rule stated:

- "This proposed rule would *clarify* the hold-harmless definition related to donations to account for the net effect of complex donation arrangements, including where the donation takes the form of the assumption of governmental responsibilities.

- "In § 433.52, the proposed definition of 'provider-related donation' would *clarify* that the assumption by a private entity of an obligation formerly performed by a unit of government where the unit of government fails to compensate the private entity at fair market value would be considered an indirect donation made from the private entity to the unit of government."

- "This proposed rule would also *clarify* that such an exchange need not arise to the level of a legally enforceable obligation."

Id. (emphases added).

As part of this regulatory clarification, the Proposed Rule "establish[ed]" a net effect standard" for determining whether a provider-based donation was bona fide. CMS's Proposed Rule expressly stated, moreover, that this newly-established "net effect" test would "incorporat[e]" the language from the Department Appeals Board decision at issue in this case. *Id*. In particular, the agency stated: "In line with the [Department Appeals] Board's reasoning, we are proposing to establish a net effect standard to look at the overall arrangement in terms of the totality of the circumstances to judge if a non-bona fide donation of cash, services or other transfer of value to a unit of government has occurred." *Id*.

B. Numerous Commenters Criticize CMS's Proposed Regulation of "Bona Fide Provider-Related Donations"

CMS received more than 10,000 comments in response the Proposed Rule. A significant number of these comments were negative. In fact, so many commenters critiqued the Proposed Rule that the agency was later forced to withdraw it.

Like many other commenters, *amicus* American Hospital Association submitted a letter criticizing the Proposed Rule's adoption of the DAB's "net effect" test. It began by explaining that, in general, "the rule would significantly change hospital supplemental payments and cripple state Medicaid program financing." American Hospital Association, Comment Letter, Medicaid Fiscal Accountability Regulation, 84 Fed. Reg. 63,722 at 1 (Jan. 29, 2020). On the very first page of its letter, *amicus* noted that "CMS claims to be clarifying policies regarding providers' role in funding the non-federal share of Medicaid, but the rule goes far beyond clarification and introduces vague standards for determining compliance that are unenforceable and inconsistent with CMS's statutory authority." *Id*. What is more, *amicus* explained, "the agency would grant itself unfettered discretion in evaluating permitted state financing arrangements through vague concepts such as

'totality of circumstances,' 'net effect,' and 'undue burden.'" *Id*. at 2. According to *amicus*, "[t]hese vague standards for determining compliance are contrary to the legal requirements of administrative law because they will make it impossible for a state to know whether its program complies with the Medicaid statute." For these and other reasons, *amicus* asked CMS to withdraw its rule in its entirety.

Amicus' comment letter also included a targeted legal analysis of the Proposed Rule's definition of "bona fide provider-related donations." It explained that "[h]ealth care providers are permitted, under federal law and regulation, to make 'bona fide' donations to governmental entities with certain restrictions as long as the donation does not have a 'direct or indirect relationship' to Medicaid payments." *Id*. at 9. The Proposed Rule, however, would

> introduce[e] a new "net effect" standard related to provider donations. This standard would allow CMS to determine whether the provider donation results "in a reasonable expectation that the provider, provider class, or related entity will receive a return of all or a portion of the donation either directly or indirectly." CMS again would use the "totality of the circumstances" concept to determine when to apply the "net effect" standard, discretion that would create confusion and uncertainty for states.

Id. As *amicus* observed, the problems with this "net effect" test went far beyond policy-related concerns about confusion, uncertainty, and impact on state Medicaid budgets. The standard also was unlawful: "The proposal includes vague language that … violates the statute," which authorizes CMS to issue regulations that "specify types of provider-related donations ... that will be considered to be bona fide provider-related donations." *Id*.

Amicus Texas Hospital Association also submitted a comment letter urging CMS to withdraw the Proposed Rule. It noted that "Texas has developed regional solutions that are well-suited to fund its obligations under the Medicaid program," but the Proposed Rule's limitations on provider-related donations likely would cause "irreparable damage to the state's health care

system—especially in rural communities where Texas leads the nation in hospital closures." Texas Hospital Association, Medicaid Fiscal Accountability Regulation, 84 Fed. Reg. 63,722 at 1, 5 (Jan. 30, 2020). As to the "net effect" test, the THA explained that it "directly contradicts [CMS'] statutory authority." *Id*. at 2. In addition, THA argued, "CMS' proposed 'net effect test' abruptly abandons years of precedent, which entire states have relied on to develop their Medicaid financing arrangements," and it was "so vague that it is without meaning" such that it violated due process. *Id*.

Amici were far from the only commenters to emphasize the Proposed Rule's many legal defects. Nor were they the only commenters that asked the agency to completely withdraw the Proposed Rule. Dozens of other commenters reached the same conclusion and made the same withdrawal request. For example:

- Twelve state health agencies submitted a comment to "express serious concerns" about the Proposed Rule.[2] These state agencies explained that the "net effect" test in the Proposed Rule was "not a reasonable interpretation" of the statute. Twelve States Agencies, Comment Letter, Medicaid Fiscal Accountability Regulation 84 Fed. Reg. 63,722 at 1 (Jan. 31, 2020). In addition, the state agency commenters "disagree[d] with CMS's statement that the [Proposed Rule] 'does not reflect any change in policy or approach, but merely codifie[s] currently prohibited practices.'" On the contrary, "the Commenting States are aware of numerous situations in which CMS has known about, and not moved to prevent, hospitals redistributing Medicaid payments …in the manner CMS now seeks to prohibit. In one State, CMS for years has annually reviewed the redistributed amounts pursuant to a written agreement acknowledging the arrangement exists." *Id*.

- Intervenor Texas Health Resources, one of the state's largest faith-based, nonprofit healthcare systems, submitted a comment urging CMS to withdraw the Proposed Rule. Taking particular aim at the Proposed Rule's changes to the regulatory scope of "provider-related donations," it explained that the "net effect" standard "would violate

[2] The Commenting state agencies were: the Colorado Department of Health Care Policy & Financing; the Illinois Department of Healthcare and Family Services; the Louisiana Department of Health; the Michigan Department of Health & Human Services; the Missouri Department of Social Services; the Missouri Department of Mental Health; the Oregon Health Authority; the New York State Department of Health; the Pennsylvania Department of Human Services; the South Carolina Department of Health and Human Services; the Tennessee Division of TennCare; and the Washington State Health Care Authority.

the statute by requiring only a 'reasonable expectation' that the taxpayer may be held harmless, rather than a 'guarantee' as required by the statue." Texas Health Resources, Comment Letter, Medicaid Fiscal Accountability Regulation, 84 Fed. Reg. 63,722 at 1 (Jan. 30, 2020). It further noted that the Proposed Rule "would introduce inconsistencies with existing regulatory language and violates the Administrative Procedure Act because it is changing policy and guidance upon which states and providers have long relied with too little rationale." *Id*. Finally, Texas Health Resources explained that the Proposed Rule's standard was unlawfully vague. Its letter stated that the "net effect" standard made it "impossible to establish a compliant standard by which to operate without fear of meeting a retrospectively determined failure to comply." *Id*. at 4. Citing cases like *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972), and *Gentile v. State Bar of Nevada*, 501 U.S. 1030, 1051 (1991), Texas Health Resources maintained that the Proposed Rule's test for a "bona fide provider-related donation" provided CMS with an illegal amount of discretion to make "ad hoc decisions on a case-by-case basis." *Id* at 4.

- The Georgia Alliance of Community Hospitals submitted a comment on behalf of its 90 non-profit member hospitals. It asked CMS to withdraw the Proposed Rule because "the MFAR contains new definitions and tests that are either ill-defined, inconsistent with prior policy, or would give CMS unfettered discretion to make determinations with far reaching consequences. Thus, rather than provide 'clarity,' the MFAR would introduce considerable uncertainty, instability, and arbitrariness to the Medicaid program." Georgia Alliance of Community Hospitals, Comment Letter, Medicaid Fiscal Accountability Regulation, 84 Fed. Reg. 63,722 at 1 (Jan. 30, 2020). The comment letter explained that the proposed changes to "bona fide provider-related donations" were particularly problematic because the MFAR "could be used to prohibit ***valid*** donations." *Id*. at 4 (emphasis in original).

- The Federation of American Hospitals, "the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States," also urged CMS to withdraw the Proposed Rule. Federation of American Hospitals, Comment Letter, Medicaid Fiscal Accountability Regulation 84 Fed. Reg. 63,722 at 1 (Jan. 31, 2020). "[S]trongly opposing the Rule," it stated that "[m]any of the provisions substantially expand CMS's regulatory authority over states and eliminate states' ability to finance their Medicaid program costs, despite CMS's lack of any statutory direction to do so." *Id*. at 2. Like other commenters, the Federation of American Hospitals sharply critiqued the unbounded discretion that the "net effect" standard afforded CMS. It argued that "the final rule appears to grant CMS discretion to investigate any conduct it desires and to reach any conclusion it desires," and that "[t]his broad scope is inconsistent with the specific tests laid out by Congress." *Id*. at 10. The comment letter further explained that any retroactive application of the "net effect" standard was unlawful. In so doing, the letter highlighted the DAB decision at issue in this case, noting that "any condition imposed on the grant of federal

moneys to state must be imposed 'unambiguously' and 'retroactive' conditions" are impermissible." *Id*. (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 & 25 (1981)).

- The Children's Hospital Association (CHA) submitted a letter on behalf of 220 children's hospitals across the country. Urging CMS to withdraw the Proposed Rule, the CHA explained that it was "particularly concerned about the lack of clarity on the new standards and how they will be applied." Children's Hospital Association, Comment Letter, Medicaid Fiscal Accountability Regulation 84 Fed. Reg. 63,722 at 1 (Jan. 31, 2020). "In our view," the CHA wrote, "the 'net effect" standard would allow CMS significant discretion to look at the 'totality of the circumstances' that the 'net effect' a[n] arrangement would have. This evaluation would include informal agreements, agreements not in writing, or agreements with no legally enforceable obligation. We are concerned these broad and subjective standards have the potential to unravel several states' provider tax arrangements." *Id*. In addition, the CHA explained: "CMS does not provide guidance on how these financing agreements will be evaluated and the subjective nature of the proposed standards creates great uncertainty given the variation and complexity of state Medicaid funding methodologies. An arrangement deemed permissible during one cycle could be deemed impermissible the next. These standards—depending on how they are applied—could disallow foundational financing streams that have been allowed for years. It has been hard for children's hospitals to identify the specific impact of these provider tax policies because of the lack of clarity of these new standards and what would be permissible or not permissible moving forward. Due to their uncertainty, the proposed standards are putting entire provider tax programs on uncertain ground—which is very troubling for states, Medicaid providers and the patients they serve." *Id*.

The list of comments urging withdrawal of the Proposed Rule and explaining its unlawfulness could go on and on. As these representative comments show, the Proposed Rule generated widespread and consistent opposition to the definition of "bona fide provider-related donations" and "net effect" test that CMS took from the DAB decision and tried to codify via notice-and-comment rulemaking.

C. CMS Withdraws Its Legally-Flawed Proposed Rule

Faced with this onslaught of negative comments, CMS withdrew the Proposed Rule. *See* Proposed Rule Withdrawal at 5,105. In so doing, the agency explicitly cited the legal critiques set forth by *amici* and others in their comment letters: "Many of the commenters stated their belief

that the proposed rule did not include adequate analysis of these matters. Numerous commenters indicated that CMS, in some instances, lacked statutory authority for its proposals and was creating regulatory provisions that were ambiguous or unclear and subject to excessive Agency discretion." *Id*. As CMS explained, "based on the considerable feedback we received through the public comment process, we have determined it appropriate to withdraw the proposed provisions at this time." *Id*.

II. The History of the Withdrawn Medicaid Fiscal Accountability Regulation Exposes the Fundamental Unfairness of the DAB's Decision

The regulatory history described above sheds important light on the DAB decision at issue in this case. It illustrates how, according to CMS itself, regulated parties like Plaintiff and Intervenors were *already* operating in an unclear legal environment when the agency *then* applied an unclear legal standard to a long-running state financing arrangement. Yet despite this acknowledged lack of clarity before *and* after the DAB's decision, CMS found the financing arrangement at issue in this case to be unlawful and disallowed over $25 million in Medicaid funding. This, *amici* respectfully submit, was fundamentally unfair.

This court need not take *amici*'s word for it, however. Throughout the regulatory history discussed above, CMS admitted to all of this uncertainty. CMS's own statements in the Proposed Rule and the subsequent withdrawal of that Proposed Rule prove that at least one of two things—and likely both—must be true.

First, the Proposed Rule repeatedly stated that it was seeking to "clarify" the definition and scope of "bona fide provider-related donations." In so "clarifying," the agency expressly incorporated the DAB's newly-minted "net effect" standard. It follows, then, that CMS thought that *before* the DAB introduced its new "net effect" standard, the state of affairs was sufficiently muddy to warrant the exercise of the Secretary's statutory authority to "specify types of provider-

related donations … that will be considered to be bona fide provider-related donations. 42 U.S.C. § 1396b(w)(2)(B). After all, if the agency believed that (1) its proposed regulation would "clarify" the definition of "bona fide provider-related donation," and (2) it adopted the "language" and "reasoning" from the DAB's decision to provide that needed clarification, *see* Proposed Rule at 63736, then it necessarily means that private actors like Plaintiff and Intervenors were operating in an unclear legal environment *before* the DAB created the new "net effect" standard.

Second, the agency's statements in its withdrawal indicate that there was, at the very least, serious force to the many commenters' concerns about the Proposed Rule. In particular, the agency chose to highlight comments questioning the agency's "statutory authority" and whether the new standards "were creating regulatory provisions that were ambiguous or unclear and subject to excessive Agency discretion." Proposed Rule Withdrawal at 5,105; *see id*. (explaining that the withdrawal was "based on considerable feedback it received" during the rulemaking process). The agency's chosen words matter. *See Int'l Union, United Mine Workers of Am. v. Dep't of Labor*, 358 F.3d 40, 43-44 (2004) ("Although the MSHA's publication of the proposed Air Quality rule certainly did not obligate it to adopt that rule (or, for that matter, any rule), the agency was not free to terminate the rulemaking for no reason whatsoever. Because the grounds upon which an administrative action must be judged are those upon which the record discloses that [the] action was based, the MSHA must provide an explanation that will enable the court to evaluate [its] rationale at the time of the decision." (internal citations and quotation marks omitted)). And those words indicate that the commenters raised persuasive concerns about the lawfulness and clarity of the Proposed Rule. As CMS itself explained, despite its best efforts to "clarify" an unclear legal landscape for state agencies and providers, CMS appeared to recognize exactly what the many commenters did: that the DAB's "net effect" standard (1) violated the 1991 Medicaid Voluntary

Contribution and Provider-Specific Tax Amendments, (2) was even more unclear than the status quo it expressly tried to clarify, or (3) both.

This regulatory history demonstrates that, one way or another, CMS impermissibly required regulated parties to operate in an unclear legal environment—and it unlawfully and retroactively penalized some of these regulated parties to the tune of $25 million for violating these unclear legal standards. Put another way, the challenged DAB decision expected a state agency and the hospital-intervenors to conform its longstanding financing arrangements to a "net effect" test that was not in place at the time and that the agency later indicated was unclear. This lack of clarity violates the most basic tenets of American law. *See FCC v. Fox Television Stations, Inc*., 567 U.S. 239, 253 (2012) ("A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required.… This requirement of clarity in regulation is essential to the protections provided by the Due Process Clause of the Fifth Amendment."); *Gen. Elec. Co.*, 53 F.3d at 1328 ("In the absence of notice—for example, where the regulation is not sufficiently clear to warn a party about what is expected of it—an agency may not deprive a party of property by imposing civil or criminal liability.… [E]lementary fairness compels clarity in the statements and regulations setting forth the actions with which the agency expects the public to comply. This requirement has now been thoroughly incorporated into administrative law." (internal citations and quotation marks omitted) (quoted in *ExxonMobil Pipeline Co.*, 867 F.3d at 578)).[3]

[3] Defendants seek to evade the import of this rulemaking process by insisting that the Proposed Rule merely codified existing law. *See* Defs' Mem. of Law in Support of Defs' Cross-Mot. for Summary Judgment and Opp. To Pl.'s and Intervenors' Mots. for Summary Judgment at 52-53 (Dkt. 59). Cherry-picking language from the Proposed Rule, Defendants argue that "the non-bona fide provider related donations provision 'ha[d] been reviewed and upheld by the [DAB] and the courts,'" and "CMS [was] 'not proposing new statutory interpretations, but [] merely proposing to codify existing policies into the Code of Federal Regulations (CFR) to improve guidance to states and other stakeholders.'" *Id*. at 52-53 (quoting Proposed Rule at 63,723). But that is no answer to the significance of the Proposed Rule (and its subsequent withdrawal). Defendants are correct that the Proposed Rule codified—and, as Defendants' Memorandum itself recognizes (at 53), *clarified*—the legal standard for "bona fide provider-related

CONCLUSION

For the foregoing reasons, this Court should grant Plaintiff's and Plaintiff-Intervenors' motions for summary judgment.

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donations." But that standard was in place at the time the Proposed Rule was issued only because the DAB had recently conjured it up in a concededly-unclear legal environment and then applied it to Plaintiff and Intervenors in a retroactive disallowance.

Defendants' arguments with respect to the withdrawal of the Proposed Rule similarly miss the mark. *First*, Defendants argue that the withdrawal leaves in place the status quo ante, including State Medicaid Director Letter #14-004. *Id*. at 53. But as explained above, the status quo ante was the problem—not the solution. As CMS conceded, that status quo ante was sufficiently hazy as to require the agency to clarify the governing legal standard by regulation. Returning to that unclear state of affairs thus does not help Defendants at all. What is more, reliance on State Medicaid Director Letter #14-0004 raises serious questions under the 1991 Medicaid Voluntary Contribution and Provider-Specific Tax Amendments. In that law, Congress authorized the Secretary to clarify the scope of the "bona fide provider-related donation" provision through regulation—not through sub-regulatory guidance or DAB decision. *See* 42 U.S.C. § 1396b(w)(2)(B) (providing that the "Secretary may *by regulation* specify types of provider-related donations described in the previous sentence that will be considered to be bona fide provider-related donations" (emphasis added). *Second*, Defendants argue that despite acknowledging the many critical comments the agency received, the withdrawal "did not reference any particular comments, nor did it endorse that view or identify the proposals to which those concerns might apply." *Id*. But this Court should not countenance this kind of slippery reasoning from a federal agency. An agency is required to clearly explain the basis for its withdrawal of proposed rules. *Williams Nat. Gas Co. v. F.E.R.C.,* 872 F.2d 438, 450 (D.C. Cir. 1989) ("The original [Notice of Proposed Rulemaking (NOPR)] in no way bound the agency to promulgate a final rule if further reflection, or changed circumstances, convinced the Commission that no regulatory change was warranted. Issuance of the NOPR did, however, oblige the agency to consider the comments it received and to articulate a reasoned explanation for its decision. We do not believe that the Commission has met these requirements."); *Int'l Union, United Mine Workers of Am.*, 358 F.3d at 43-44 (same). CMS has no excuse for not explaining with sufficient specificity which comments formed the basis for its withdrawal, and it certainly should not be allowed to affirmatively hide behind that lack of specificity to distance itself from the types of critical comments it chose to highlight in its withdrawal. Put simply, CMS cannot pile unclarity on top of unclarity to defend its disallowance of $25 million in funding for Texas' neediest patients.

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/s/ Jordan Campbell

Jordan Campbell
Brown Fox PLLC
8111 Preston Road, Suite 300,
Dallas, Texas 75225
(214) 396-9284
jordan@brownfoxlaw.com

Chad I. Golder (*Pro Hac Vice* Pending)
514 6th Street, NE
Washington, DC 20002
(203) 506-0670
chadgolder@gmail.com

Counsel for Amici Curiae

CERTIFICATE OF SERVICE

Pursuant to Federal Rule of Civil Procedure 5(d)(1)(B), as amended, no certificate of service is necessary because this document is being filed with the Court's electronic system.

Dated: April 27, 2021

/s/ Jordan Campbell
Jordan Campbell