IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS TYLER DIVISION

THE STATE OF TEXAS; TEXAS	§
HEALTH AND HUMAN SERVICES	§
COMMISSION	§
Plaintiffs,	§
	§
v.	§ CIVIL ACTION NO. 6:21-CV-191
	§
CHIQUITA BROOKS-LASURE, in	§
her official capacity as	§
Administrator of the Centers	§
for Medicare & Medicaid Services,	§
et al.	§
Defendants.	§

DEFENDANTS' SURREPLY IN SUPPORT OF DEFENDANTS' COMBINED OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

TABLE OF CONTENTS

1.	Argume	III	1
a.	Plainti	iffs' Suit Should Be Dismissed For Lack of Subject Matter Jurisdiction	1
	i.	Plaintiffs have not established standing or ripeness	1
	ii.	Plaintiffs do not challenge a final agency action	4
b.	Plainti	iffs Have Not Established An Entitlement to Preliminary Injunctive Relief	5
	i.	Plaintiffs have not clearly established that they will suffer irreparable harm in the absence of a preliminary injunction.	5
	ii.	Plaintiffs have not clearly established a likelihood of success on the merits.	9
		1. CMS's January Approval Was Made In Excess of Authority	9
		2. If CMS Took Action Through the April 16 Letter, It Acted Within Its Authority	11
	iii.	Plaintiffs have not clearly established that the balance of equities or public interest favor a preliminary injunction	13
II.	Conclus	ion	14

TABLE OF AUTHORTIES

CASES

Adar v. Smith, 639 F.3d 146 (5th Cir. 2011)	3
Bennett v. Spear, 520 U.S. 154 (1997)	4
Cargill v. Barr, 502 F. Supp. 3d 1163 (W.D. Tex. 2020)	2
DHS v. Regents of the University of California, 140 S. Ct. 1891 (2020)	12, 13
Forrest General Hospital v. Azar 926 F.3d 221 (5th Cir. 2019)	11
Hardy Wilson Mem. Hosp. v. Sebelius, 616 F.3d 449 (5th Cir. 2010)	9
Lawyers United, Inc. v. United States, Case No. 19-cv-3222, 2020 U.S. Dist. LEXIS 114486 (D.D.C. June 29, 2020)	14
Macktal v. Chao, 286 F.3d 822 (5th Cir. 2002)	11
National Park Producers Council v. EPA, 635 F.3d 738 (5th Cir. 2011)	4
North Georgia Bldg. & Constr. Trades Council v. Goldschmidt, 621 F.2d 697 (5th Cir. 1980)	9
Pope v. Shalala, 998 F.2d 473 (7th Cir. 1993)	9
U.S. DOL v. Kast Metals Corp., 744 F.2d 1145 (5th Cir. 1984)	2
STATUES	
42 U.S.C. § 431.416	8, 9
REGULATIONS	
42 CFR § 430.3	2
45 C.F.R. part 16 App'x	1. 2

Case	6:21-cv-00191-JCB	Document 37	Filed 08/12/21	Page 4	of 20 Pag	aeID#:	3243

45 C.F.R. § 16.22	3,	4
45 C.F.R. § 16.7		1

I. Argument

The Court should deny Plaintiffs' Motion for Preliminary Injunction for all of the reasons stated herein and in Defendants' Opposition, but most straightforwardly because Plaintiffs have not demonstrated any likelihood that they will suffer irreparable harm. Most of the harms alleged by Plaintiffs are not tied to the January 15 Letter at issue in this case and thus the requested preliminary injunction would provide no relief. To the extent any alleged harms are tied to the January approval, CMS is bound by the existence of the pending DAB appeal to treat that approval as in force so there is also no imminent threat of harm. The court can deny Plaintiffs' motion for that reason alone, or any of the others explained in this brief or Defendants' Opposition.

a. Plaintiffs' Suit Should Be Dismissed For Lack of Subject Matter Jurisdiction i. Plaintiffs have not established standing or ripeness

Plaintiffs bear the burden of establishing both standing and ripeness, and they have failed to directly address either in their Preliminary Injunction Motion ("PI Mot."), ECF No. 11, or Reply, ECF No. 29. As explained in Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction and Motion to Dismiss ("Opp."), ECF No. 23 at 8-12, 14, and *infra* at 6-7. Plaintiffs have no injury in fact that is actual and imminent and not conjectural or hypothetical, because they are currently receiving relief duplicative of their requested preliminary injunction as a result of the pending Departmental Appeal Board ("DAB") appeal. Consequently, Plaintiffs' alleged injury relating to the extension of the demonstration project is not imminent and their claims are not ripe at least until the DAB appeal concludes and, even then, only if the DAB upholds CMS's April 16 Letter.¹

¹ Plaintiffs' brief and generic discussion of state quasi-sovereign interests does not address the standing issue in this case. Reply at 19. Plaintiffs lack standing because there is no actual or imminent harm that is real and not conjectural and caused by the voiding of the January 15

Plaintiffs contend that the DAB lacks jurisdiction to consider Texas's appeal, that they chose to file, and that the Court should therefore find that the DAB appeal is improper and proceed as though it is not pending. This argument fails for several reasons. First, the DAB is empowered by regulation to determine its own jurisdiction over a given matter. *See* 45 C.F.R. § 16.7; 45 C.F.R. Part 16 App'x A(G). Second, Plaintiffs have not challenged the DAB's jurisdiction in this case, *See generally* Compl. ECF No. 1, nor could they have brought such a challenge before the DAB has had an opportunity to consider its own jurisdiction in the first instance. Thus, any opinion of the Court as to the DAB's jurisdiction would be merely advisory and would not change Defendants' obligation to comply with the DAB regulations during the pendency of the appeal.

Third, even if the Court were in a position to pass on the question of the Board's jurisdiction in this case, there is no basis on which to conclude that DAB jurisdiction is lacking. Plaintiffs' argument that the April 16 Letter cannot be a "voiding" because CMS did not use the specific words "void" or "voiding" elevates form over function. The April 16 Letter identifies the January 15 approval as void because the award it granted "was not authorized by...regulation." 45 C.F.R. Part 16 App'x A(C)(a)(4); Ex. 2, April 16 Letter, ECF No. 23-2 at 1-2. Moreover, the DAB is independent from CMS, and like a Court must look past the agency's label to the substance of its action. *Cf. Cargill v. Barr*, 502 F. Supp. 3d 1163, 1184 (W.D. Tex. 2020) (quoting *U.S. DOL v. Kast Metals Corp.*, 744 F.2d 1145, 1149 (5th Cir. 1984) ("The Court is not bound by an agency's choice of label for its action.")). Plaintiffs' argument that the April 16 Letter does not substantively

approval. As described *infra*, Plaintiffs are already receiving the relief that they request through the preliminary injunction motion, and the "market contraction" alleged is premised on the expiration of DSRIP and/or the demonstration project as a whole, neither of which are implicated by the January 15 Letter.

meet the regulatory definition of "voiding," fails for the same reason. The April 16 Letter clearly recognizes that the January approval was made in excess of the agency's authority, which is the definition of a void decision under the applicable regulation. 45 C.F.R. Part 16 App'x A(C)(a)(4) ("A voiding (a decision that an award is invalid because it was not authorized by statute or regulation...)."). It is irrelevant that the April 16 Letter does not specifically inform Texas of its right to appeal to the DAB. See Reply at 8. The regulations expressly provide general appeal rights for challenges to § 1315 determinations, 42 CFR § 430.3, and Texas clearly understood that its challenge at least potentially fell within the category of claims heard by the Board because it filed an appeal. Additionally, there is no statutory or regulatory requirement that CMS provide notification of appeal rights. The manual Plaintiffs cite neither mandates any action on the part of CMS, nor does it have the legal force of a regulation. DAB Appellate Division Practice Manual, available at https://www.hhs.gov/about/agencies/dab/different-appeals-at-dab/appeals-toboard/practice-manual/index.html#1 (accessed August 12, 2021) ("An adverse determination made by [an agency] should inform you of any applicable appeal rights, but it is possible that this information may be omitted.") (emphasis added); see also id. ("[T]his manual does not override anything in regulations or statutes that govern cases before the Board... [t]he information provided here is for general guidance only.").

Additionally, Plaintiffs have failed to explain how many of the harms they allege are attributable to the voiding of CMS's January 15 Letter, the subject of this litigation. *See infra*; Ex. 1, January 15 Letter, ECF No. 23-1. Thus, Plaintiffs have not established how these injuries could be redressed by either the requested preliminary injunction or a favorable decision on the merits. *See e.g.*, *Adar v. Smith*, 639 F.3d 146, 150 (5th Cir. 2011) ("In order to establish standing, a plaintiff must show that...a favorable decision is likely to redress the injury.").

ii. Plaintiffs do not challenge a final agency action

Plaintiffs allege that the Court has jurisdiction to consider CMS's April 16 Letter, because it marks the consummation of the agency's decision-making process and generates legal consequences for Plaintiffs. First, Plaintiffs ignore the fact that the April 16 Letter cannot be final agency action because it does not represent any action taken by CMS at all. *See* Opp. at 20-21. The April 16 Letter serves merely as a notice to Texas that the January 15 Letter was made in excess of the agency's authority and is therefore void. It is the voiding of the January 15 letter by operation of law, and not any statement or action in the April 16 Letter, that returns Plaintiffs to the requirements of the demonstration project in its previously approved form.

Second, even if the April 16 Letter is agency action taken under CMS's inherent authority to reconsider prior decisions, Opp. at 21-22, it is not final agency action. Final agency action "must be one by which 'rights or obligations have been determined' or from which 'legal consequences will flow." *National Park Producers Council v. EPA*, 635 F.3d 738, 755 (5th Cir. 2011) (quoting *Bennett v. Spear*, 520 U.S. 154, 178 (1997)). No legal consequences flow from the April 16 Letter while the DAB appeal is pending because CMS may not take any action to implement the letter during the pendency of the appeal. 45 C.F.R. § 16.22(a). If the DAB eventually determines the merits in favor of Plaintiffs, then the April 16 Letter will be invalidated and the January 15 approval will be controlling. "Agency actions that have no effect on a party's rights or obligations are not reviewable final agency actions." *National Park*

Producers, 635 F.3d at 755. Moreover, once the DAB decision issues, Plaintiffs will have the opportunity to challenge that final agency decision.^{2,3}

b. Plaintiffs Have Not Established an Entitlement to Preliminary Injunctive Relief

Plaintiffs do not dispute that they are seeking a mandatory injunction and must therefore meet a heightened standard to obtain a preliminary injunction. Opp. at 7. Plaintiffs have failed to satisfy even one of the requirements of a typical prohibitory preliminary injunction, so it is beyond doubt that the mandatory injunction they pursue must be denied.

i. Plaintiffs have not clearly established that they will suffer irreparable harm in the absence of a preliminary injunction.

As explained in detail in Defendants' Opposition, Plaintiffs are currently receiving the relief that they request in their preliminary injunction motion by operation of DAB regulation 45 C.F.R. § 16.22. Opp. at 8. Much of the harm that Plaintiffs allege is also speculative, but more importantly, it is not related to the January 15 Letter and thus would not be remediated by the requested preliminary injunction requiring CMS to implement the January 15 Letter.

First, during the pendency of the DAB appeal, § 16.22 requires that the agency "shall take no action to implement" the challenged decision, in this case the April 16 Letter. Although Defendants maintain that the April 16 Letter was not agency action and that the January 15 Letter is void, in order to comply with this requirement they are nevertheless acting as if the

² As explained *infra* and in the Supplemental Cash declaration, Plaintiffs' allegations that the April 16 Letter created practical consequences related to independent approvals not dictated by the January 15 or April 16 Letters, Reply at 3-5, are both incorrect and irrelevant to the merits of this suit and would not be implicated by the requested preliminary injunction. Supp. Cash Decl. ¶¶ 4-11.

³ Defendants do not contend that Plaintiffs are required by statute to exhaust DAB appeal procedures. But Plaintiffs have chosen to engage in the DAB appeal process, and it is currently ongoing. Thus, in addition to the Court lacking jurisdiction, the interests of judicial economy favor not duplicating the Board's consideration, which is currently providing Plaintiffs the identical relief they seek in this case.

January approval is in force while the DAB appeal is pending. Opp. at 8; Supplemental Declaration of Judith Cash, Ex. 8 ¶ 2.4 Plaintiffs claim that Defendants have not in fact been treating the January 15 Letter as effective, Reply at 4-5, but this argument does not bolster their position for two reasons. First, Plaintiffs are simply incorrect that CMS has failed to meet various requirements of the January 15 Letter. See generally Supp. Cash Decl. Although the January approval requires Texas to produce various deliverables, there are no specific deliverables required of CMS. See id. at 4-5, 7, 10-11. The Special Terms and Conditions of the January 15 Letter propose goal timelines for CMS to "work collaboratively" with Texas to process certain deliverables required of the state. Id. at 5. However, even if these goals created any legal obligations on CMS, which they do not, to the extent Plaintiffs have made submissions that generate such deadlines, none of those deadlines have yet passed. *Id.* at 8-10, 13-15. Second, even if Plaintiffs were correct that Defendants had failed to carry out certain aspects of the January approval, compliance with that approval is nonetheless required by regulation. Plaintiffs are thus already entitled during the pendency of the DAB appeal to the relief they seek through the preliminary injunction and have an avenue before the DAB to challenge any specific failure to comply with the January approval pursuant to 45 C.F.R. § 16.22. Additionally, the uncompensated care pool ("PHP-CCP"), which was approved by the January 15 Letter, can be implemented during the pendency of the DAB appeal and contrary to Plaintiffs' allegations, Reply at 18, cannot be the source of any imminent irreparable harm.⁵

_

⁴ These positions are not inconsistent. *See* Pls.' Reply at 4-5. Whether the January approval is legally void is one of the issues before the DAB and thus the agency would not be in compliance with the regulation if it presupposed that the approval was made without authority.

⁵ The DAB regulation does not, however, prohibit Defendants from recouping funds improperly expended under the void approval in the event Defendants ultimately succeed in the DAB appeal and/or this lawsuit.

Second, Plaintiffs continue to attempt to muddle the operative facts in order to support a claim of irreparable harm that simply is not related to the substance of the preliminary injunction requested. The evidence presented by Plaintiffs clearly ties the alleged harm to the expiration of DSRIP on September 30, 2021, and the eventual expiration of the demonstration project ("THTQIP") as a whole on September 30, 2022. But, as Defendants explained and Plaintiffs admit, Reply at 18, the January approval did not extend DSRIP and therefore the requested preliminary injunction could not cure any harms the expiration of DSRIP would allegedly cause, including the "market contraction" Plaintiffs allege. See PI Mot. at 4, 13, 32-33. Plaintiffs accuse Defendants of a lack of candor to the Court for stating that Texas did not make a request to extend DSRIP. Reply at 14. But Plaintiffs did not in fact make a proper request to CMS to extend DSRIP as required by regulation with the necessary supporting documentation. Supp. Cash Decl. ¶ 3. More importantly, for purposes of the claims in this lawsuit, no request to extend DSRIP or approval of such a request was a part of the January 15 Letter and therefore any harms allegedly flowing from the expiration of DSRIP are not relevant to the preliminary injunction motion under consideration or indeed to the underlying merits. See id. Additionally, as explained supra, the PHP-CCP will be funded during the pendency of the DAB appeal, but even if that were not the case, it was never intended to be a replacement for DSRIP, and provides 20% or less of the funding provided by DSRIP. Ex. 3, Declaration of Judith Cash, ECF No. 23-3, ¶ 14.

Similar to DSRIP, the new state directed payments Plaintiffs reference in their Motion are not encompassed within the January 15 Letter, and require independent approval from CMS that would not be secured by the requested preliminary injunction. *See* PI Mot. at 12-13; Reply at 17; Supp. Cash Decl. ¶¶ 4-11. Other payments requiring annual approval, Reply at 17, are also separate from the January 15 Letter. Supp. Cash Decl. ¶¶ 4-11.

Plaintiffs also still have not identified any specific harms that would result from the lack of a preliminary injunction as opposed to the eventual expiration of the entire demonstration project on September 30, 2022.6 They have not explained why any harm that allegedly flows from the voiding of the particular extension approved by the January 15 Letter, as opposed to the expiration of DSRIP or lack of approval of state directed payments, is irreparable when multiple avenues exist to secure an extension of the demonstration project and Plaintiffs have begun all of them. Not only is there an adequate judicial remedy in the resolution of the merits of this case, but the same is true of the DAB appeal and Plaintiffs' new application for extension of THTQIP.

Moreover, because the merits of this case and the DAB appeal are still undecided, having a preliminary injunction would not actually eliminate any alleged harm stemming from long-term uncertainty. The Defendants could still prevail on the merits, thereby invalidating all actions taken by Plaintiffs (and any of the organizations whose interests they purportedly represent) on the basis of preliminary relief. Plaintiffs say they cannot wait months for the merits decision at the DAB or from this Court, but ignore the fact that either or both decisions could be made in favor of Defendants. If providers make plans on the basis of any preliminary relief that is awarded, as Plaintiffs claim they will, Pls.' Reply at 17-19, they could face even more instability in the future if the DAB or this Court were to eventually decide the merits in favor Defendants.

⁶ Plaintiffs' argument about their alleged sunk costs also does not show irreparable harm for which preliminary relief is appropriate. *See* Reply at 20. That money and time has already been expended, regardless of the entry of a preliminary injunction or even the possibility of Plaintiffs eventually prevailing on the merits. Moreover, as described *supra*, Plaintiffs are already receiving all of the relief that they request through the duration of the DAB appeal.

ii. Plaintiffs have not clearly established a likelihood of success on the merits.

As explained *supra*, Plaintiffs have established neither standing nor ripeness and the purported action they challenge is not final agency action. Therefore, the Court lacks subject matter jurisdiction to consider Plaintiffs' claims and they have no likelihood of success on the merits. However, even if the Court finds that it has jurisdiction, Plaintiffs have failed to clearly establish a likelihood of success on the merits, because they cannot show that the January 15 approval was made under CMS's lawful authority.

1. CMS's January Approval Was Made In Excess of Authority

Plaintiffs spend pages of their reply arguing that, in general, CMS has statutory and regulatory authority to waive the requirements of public notice and comment for § 1315 extension requests. See Reply at 10-12. Defendants of course do not dispute that CMS has such authority under certain conditions, but the authority is explicitly limited by the agency's regulations. It is an indisputable tenet of administrative law that "the agency is bound to comply with the regulations it promulgates." Hardy Wilson Mem. Hosp. v. Sebelius, 616 F.3d 449, 461 (5th Cir. 2010) (quoting North Georgia Bldg. & Constr. Trades Council v. Goldschmidt, 621 F.2d 697, 710 (5th Cir. 1980)); see also id. ("The Secretary is bound by her own regulations...until she changes them." (quoting Pope v. Shalala, 998 F.2d 473, 486 (7th Cir. 1993)). In the case of exemptions from public notice and comment for approval or extension of a demonstration project, CMS may not excuse a state unless it satisfies specific conditions related to the reason for, and urgency of, the request. See generally 42 U.S.C. § 431.416. Consequently, an exemption request that does not satisfy these conditions is beyond the agency's authority to approve and any such purported approval is thus void. See Opp. at 16-17.

Defendants Opposition, as well as the April 16 Letter, explain in detail why Plaintiffs' public notice and comment exemption request did not satisfy the conditions required to permit

lawful approval. Opp. at 16-20; April 16 Letter, Ex. 2 at 2-4. Plaintiffs' arguments to the contrary are unavailing. First, Plaintiffs' discussion of the COVID-19 survey they conducted, Reply at 12, whether or not it supports their request for extension of the demonstration project as a whole, did not provide a reason to exempt the state from ordinary notice and comment rules. The fact that Texas sought to extend THTQIP beyond September 30, 2022, in part because of the effects of COVID-19, in no way demonstrates that following the mandated notice and comment procedures in November 2020 "would undermine or compromise the purpose of the demonstration." 42 U.S.C. § 431.416(g)(3)(iii). As noted in Defendants' Opposition, complying with the federal public notice and comment requirements would have taken as little as 45 days and at least part of this period could have proceeded concurrently with the 30 days that elapsed between Defendants' acknowledgment of Plaintiffs' application, see Cash Decl., ECF No. 23-3, Ex. E (pg. 25), and the January 15 approval. Second, CMS's position that § 431.416(g)(1) requires a program to "address" an emergency directly in order to justify a public notice and comment exemption, see April 16 Letter, Ex. 2 at 3, is a reasonable interpretation of the agency's own regulation and Plaintiffs' unsupported disagreement does not demonstrate otherwise.8

Third, for the reasons outlined in Defendants' Opposition, Plaintiffs have neither demonstrated that the "circumstances constituted an emergency" nor that the "effects could not have reasonably been foreseen." Opp. at 18-19. Plaintiffs' arguments to the contrary concern

⁷ Plaintiffs claim that Defendants do not challenge the adequacy of their state notice and comment process and other requirements antecedent to applying for the demonstration project at issue in the current case. Reply at 11. Defendants do not challenge that process for purposes of this preliminary injunction motion only. Defendants reserve the right to challenge those processes, which were in fact deficient in that they occurred after Texas's application for extension was made to CMS, at a later stage. *See* 42 C.F.R. § 431.408.

⁸ Moreover, the January 15 Approval does not in any way alleviate the immediate effects of the COVID-19 pandemic on Texas healthcare providers.

their reason for seeking an extension of THTQIP, which, at the time, did not expire for another 22 months, not their justification for seeking an exemption from the public notice and comment requirements. *See* Reply at 13-14.

2. If CMS Took Action Through the April 16 Letter, It Acted Within Its Authority

Defendants' Opposition explains in detail their alternative position that CMS, in its April 16 Letter, acted pursuant to its inherent authority to reconsider its prior decision. Opp. at 21-23. Contrary to Plaintiffs' argument, the Fifth Circuit has recognized the existence of this authority independent of any specific statutory or regulatory grant. *See Macktal v. Chao*, 286 F.3d 822, 825-26 (5th Cir. 2002). *Forrest General Hospital v. Azar*, on which Plaintiffs rely, is simply inapposite. 926 F.3d 221 (5th Cir. 2019). In that case, HHS argued that it had statutory authority to exclude certain types of uncompensated care days from the calculation of Medicaid disproportionate share hospital payments. *Id.* at 233. The Court agreed but found that HHS could not rely on that authority because it had already exercised the same authority to include those types of patient days in the calculation. *Id.* Conversely, here, CMS determined that it never had statutory or regulatory authority in the first instance to approve the demonstration extension without notice and comment. CMS's reconsideration in the April 16 Letter therefore was not a "take-back" of an already approved extension because of a change in policy, but a decision that the purported approval was never properly granted because it was beyond CMS's authority.

Plaintiffs also argue that Defendants' reconsideration was arbitrary and capricious because CMS did not consider Plaintiffs' reliance interests or other alternatives to the voiding of the January approval. First, CMS did consider the possibility of reliance interests and reasonably concluded that no relevant interests had accrued. *See* April 16 Letter, Ex. 2, at 7. Plaintiffs' disagreement with the conclusion reached by CMS does not erase the fact that the agency

considered this issue. Plaintiffs primarily rely on DHS v. Regents of the University of California, to argue that CMS "failed to consider...important aspect[s] of the problem." 140 S. Ct. 1891, 1910 (2020) (citation omitted). However, this case is easily distinguishable. First, the timing of the January and April Letters belie Plaintiffs' claim that reliance interests like those contemplated in Regents could have arisen. The Regents court cautioned that agencies "must be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account." Id. at 1913 (emphasis added and citation omitted). Plaintiffs' assertion that serious reliance interests arose during the 90 days between the two Letters, when absent the January approval the demonstration project would nevertheless have continued in essentially the same manner for another 22 months, is untenable. Moreover, whether an agency decision is lawful is a factor in determining whether alleged reliance interests are serious and legitimate. See id. at 1913-14 ("reliance interests in benefits that [the agency] views as unlawful are entitled to no or diminished weight."); see also Amicus Brief of Every Texan, ECF No. 25-1, at 10-12. Here Plaintiffs were aware that the January approval was made under unusual circumstances, and barely 90 days later the illegality of that decision was acknowledged by CMS itself. See Amicus Brief at 10-12. Contrary to Plaintiffs' construction of the case, Regents only obligates agencies "to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." Regents, 140 S. Ct. at 1914. CMS made that assessment, and determined that no significant reliance interests had accrued in the short time between the Letters. See April 16 Letter at 7.

Second, Plaintiffs' argument that *Regents* imposed a requirement on CMS to consider alternatives to voiding the January approval is also unsupported. Voiding the January 15 Letter did not have the breadth or the finality of the decision to wind down the Deferred Action for

Childhood Arrival ("DACA") policy. See Regents, 140 S. Ct. at 1910-11. Despite Plaintiffs' attempts to muddle the facts, the April 16 Letter did not terminate the demonstration project or prohibit its extension, but merely acknowledged that the particular extension approval at issue was unlawful. Unlike the rescission of DACA, CMS expected, and in fact invited, Plaintiffs to reapply for extension of the demonstration project. See April 16 Letter at 2, 7. In addition, the Regents court found that the agency's decision to rescind all aspects of DACA was arbitrary and capricious because the legal conclusion on which that determination rested invalidated only the "benefits" authority of the statute, not the "forbearance" authority. Id. at 1911-12. In the instant case, there are no other parts of the January approval that could have been salvaged as an alternative to voiding the Letter because the entire approval rests upon a threshold legal question: can approval be granted without public notice and comment? CMS determined that there was no authority to grant the exemption from public notice and comment based on the justification provided by the state and therefore there were no "alternatives" to consider "within the ambit of the existing policy." Id. at 1913 (citation omitted).

Plaintiffs have not shown that the Court has jurisdiction to consider this case, that CMS acted within its authority in granting the January 15 Letter despite the absence of public notice and comment, or that CMS acted outside its authority in issuing the April 16 Letter. Thus, Plaintiffs have not demonstrated a likelihood of success on the merits.

iii. Plaintiffs have not clearly established that the balance of equities or public interest favor a preliminary injunction

As explained herein and in Defendants' Opposition, Plaintiffs bear the burden of establishing that each prong of the preliminary injunction analysis clearly favors them in both fact and law. Because Plaintiffs are not subject to any harm and the requested preliminary injunction would not provide them with any relief, they have failed to establish that either the

balance of equities or the public interest favors them. Moreover, Plaintiffs are incorrect that the public interest would not "suffer additional harm by entering the injunction," Reply at 20, when the preliminary injunction would be duplicative of the relief already provided by the DAB appeal. *See Lawyers United, Inc. v. United States*, Case No. 19-cv-3222, 2020 U.S. Dist. LEXIS 114486, at *21 (D.D.C. June 29, 2020) ("[T]he public is not benefitted by an unnecessary injunction that does not stop irreparable harm."). Imposing an unnecessary injunction that must be monitored by the Court is a significant waste of judicial resources and is contrary to the public interest.

II. Conclusion

For the reasons stated herein, in the attached exhibit, and in Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction and Motion to Dismiss, the Court should deny Plaintiffs' Motion for Preliminary Injunction and dismiss this suit for lack of subject matter jurisdiction.

Dated: August 12, 2021

Respectfully Submitted,

BRIAN M. BOYNTON
Acting Assistant Attorney General

NICHOLAS J. GANJEI Acting United States Attorney

MICHELLE BENNETT Assistant Branch Director

/s/ Keri L. Berman

KERI L. BERMAN
Trial Attorney
United States Department of Justice
Civil Division
1100 L Street NW, Rm. 11206
Washington, DC 20005

Tel: (202) 305-7538

Email: Keri.L.Berman@usdoj.gov

Attorneys for Defendants

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was served on all counsel of record by operation of the court's electronic filing system and can be accessed through that system.

DATED: August 12, 2021

/s/ Keri L. Berman
KERI L. BERMAN
Trial Attorney
United States Department of Justice
Civil Division
1100 L Street NW, Rm. 11206
Washington, DC 20005
Tel: (202) 305-7538

Email: Keri.L.Berman@usdoj.gov

Defendants' Exhibit 8 Supplemental Declaration of Judith Cash

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF TEXAS TYLER DIVISION

THE STATE OF TEXAS; TEXAS HEALTH AND HUMAN SERVICES COMMISSION

Plaintiffs,

v.

CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare & Medicaid Services, et al.

Defendants.

Case No.: 6:21-cv-00191

SUPPLEMENTAL DECLARATION OF JUDITH CASH

- I, Judith Cash of the Center for Medicaid and CHIP Services (CMCS) at the Centers for Medicare & Medicaid Services (CMS), previously submitted a Declaration in this case, ECF No. 23-3, and incorporate by reference all of my statements in that Declaration. I declare that the following supplemental statements are true and correct to the best of my knowledge and belief, and that they are based on my personal knowledge as well as information provided to me in the ordinary course of my duties.
- 1. Due to the nature of my official duties, I am familiar with decision-making processes at CMCS and the process for approving applications for Medicaid section 1115 demonstration projects, as well as applications to extend or amend approved projects.

2. The Departmental Appeals Board's (DAB) regulations provide that, once a state files an appeal before the DAB, CMS "shall take no action to implement the final decision appealed." 45 C.F.R. § 16.22. CMS notified Texas on April 16, 2021 that CMS's January 15, 2021 approval of Texas's extension application for its section 1115 Medicaid demonstration project was unlawful. Texas filed its DAB appeal challenging CMS's April 16 letter on May 14, 2021. Since Texas filed its DAB appeal on May 14, 2021, CMS has taken no action on its April 16, 2021 letter and has proceeded on the assumption that the January 2021 approval will remain in effect while the DAB appeal is pending.

DELIVERY SYSTEM REFORM INCENTIVE PAYMENT (DSRIP) POOL

3. As stated in my previous Declaration, Texas did not submit an amendment to the demonstration to extend DSRIP. Texas sent a letter to the CMS Administrator purporting to request that "CMS extend the DSRIP program with \$2.49 billion in continued funding for the final demonstration year of the current 1115 Healthcare Transformation Waiver" on October 16, 2020. Grady Decl., Ex. B, at 4, ECF No. 29-1. That letter did not constitute an application under CMS's regulations, *see* 42 C.F.R. § 431.412, or include any of the application materials provided on CMS's website. *See* CMS, 1115 Application Process, https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-application-process/index.html. When Texas submitted its extension application for its demonstration project on November 30, 2020, Texas stated that it was not requesting to extend DSRIP. *See* First Cash Decl., Ex. E, at 4, ECF No. 23-3 ("There are no proposed changes to the healthcare delivery system under the demonstration."). Accordingly, CMS does not consider the October 16, 2020 letter from Texas to be a request for an extension of Texas's DSRIP program.

STATE DIRECTED PAYMENTS

- 4. Texas's state directed payments are separate from the January 15, 2021 approval at issue in this litigation. While the special terms and conditions (STCs) included with the January 15 Letter include goal timelines for CMS and Texas to discuss Texas's state directed payment requests, they expressly state that "[d]escription of a particular state directed payment in these STCs does not qualify as CMS approval, nor does it negate the approval and other requirements of 42 C.F.R. § 438.6(c)." Grady Decl., Ex. C, at 32 of 74, ECF No. 29-1 (STC 29). The STCs do not prescribe a deadline for CMS to approve (or disapprove) Texas's requested state directed payments, nor do they require CMS to approve those requested payments at all. STCs 30 to 34 outline CMS's review process for Texas's requests for state directed payments. See Grady Decl., Ex. C, at 32–33 of 74, ECF No. 29-1. To the extent those STCs create obligations for CMS in reviewing Texas's requested state directed payments, CMS has complied with those requirements.
- 5. STC 30 provides generally that "the state and CMS will work collaboratively towards consideration of approval of state requests and will adhere to the milestones outlined in the subsequent STCs." *Id.*, Ex. C, at 32 of 74, ECF No. 29-1. CMS has worked collaboratively and in good faith with Texas in reviewing Texas's requested state directed payments, as set forth in the table below.
- 6. STC 31 provides that CMS will furnish its requests for information that CMS needs to assist it in evaluating Texas's requested state directed payments to Texas within 30 calendar days of receiving Texas's completed request. *Id.* As demonstrated in the table below, Texas submitted requests for five state directed payments, each which CMS deemed complete between March 19 and April 1, 2021. CMS thereafter engaged in phone calls with Texas and

made a good-faith effort to furnish requests for information to Texas within 30 days of deeming Texas's request to be complete.

- 7. STC 32 provides that "Texas will provide responses in writing" to CMS's requests for more information "within 15 calendar days following receipt of the requests for additional information." *Id.* This STC does not impose any obligation on CMS.
- 8. STC 33 provides that CMS will "evaluate any information provided by the state by phone or in writing," that "[i]f CMS determines that the request for approval is complete and complies with the requirements of 438.6(c), CMS will notify the state in writing within 20 calendar days of receipt of the state submitting complete responses to requests for information that CMS anticipates issuing a formal decision letter within 20 calendar days." *Id.*, Ex. C, at 32– 33 of 74, ECF No. 29-1. That STC further provides that "[i]f CMS identifies any outstanding matters that need technical or substantive modification in order for CMS to make a final decision, CMS will identify the matters and provide notification to the state in writing within 20 calendar days of receipt of the state submitting complete responses to requests for information." Id. This STC does not require CMS to approve or disapprove Texas's state directed payment requests by a certain deadline. CMS has complied with this STC. After receiving Texas's responses to the Round 1 questions, CMS submitted a second round of questions, working in good faith to try to respond to Texas's responses within the 20-day goal. CMS also submitted a third round of questions about Texas's CHIRP state directed payment request, as shown in the table below.
- 9. STC 34 provides that "[i]f the state is notified by CMS that further modifications to the request are required, CMS and the state will meet by phone or other means at least every 2 business days until final consideration of the proposal." *Id.*, Ex. C, at 33 of 74, ECF No. 29-1.

CMS has not engaged in phone calls with Texas every two business days because it has not yet concluded that "further modifications to the request are required."

10. To the extent the STCs impose specific requirements on CMS, CMS has worked in good faith to comply with these timelines. A chart showing CMS's engagement with Texas on its requested state directed payments is provided below:

	CHIRP	QIPP	TIPPS	RAPPS	BHS
Submission Date from Texas	3/8/21	3/11/21	3/5/21	3/25/21	3/29/21
CMS Determined Submission Complete (CMS E- mail to Texas)	3/19/21	3/24/21	3/22/21	3/30/21	4/1/21
Call with Texas and CMS/DMCP for General Overview of CHIRP and TIPPS Submissions	3/23/21	n/a	3/23/21	n/a	n/a
Calls with Texas and CMS Federal Review Team (FRT) to Discuss Submissions	3/29/21	3/31/21	3/31/21	4/8/21	4/8/21
CMS Round 1 Questions Sent to State (CMS E-mail to Texas)	4/21/21	4/30/21	5/7/21	5/21/21	5/14/21
State Responses to Round 1 Questions Received By CMS (E-mail from Texas)	5/5/21	5/14/21	5/21/21	6/4/21	5/28/21
CMS Round 2 Questions Sent to	5/28/21	6/8/21	6/17/21	7/1/21	6/25/21

State (CMS E-mail to Texas)					
State Responses to Round 2 Questions (E-mail from Texas)	6/11/21	6/21/21	7/1/21	7/8/21	7/6/21
CMS Round 3 Questions Sent to State (CMS E-mail to Texas)	7/8/21	n/a	n/a	n/a	n/a
State Responses to Round 3 Questions (E-mail from Texas)	7/14/21	n/a	n/a	n/a	n/a

11. Other than setting forth procedures for CMS's review of Texas's requested state directed payments as outlined above, the January 2021 approval extending Texas's 1115 demonstration project did not obligate CMS to take any particular action with respect to those requested state directed payments.

CMS'S ACTIONS RELATED TO THE PUBLIC HEALTH PROVIDERS CHARITY CARE POOL (PHP-CCP)

- 12. The STCs included with CMS's January 15 Letter do not require CMS to take any action on the new uncompensated care pool included in that approval, the Public Health Providers Charity Care Pool (PHP-CCP). Those STCs set forth several deliverables that Texas must meet throughout the life of the demonstration project, but they do not require CMS to take any action when it receives those deliverables from Texas.
- 13. STC 39(b) requires Texas's Health and Human Services Commission (HHSC) to "revise, test, and obtain CMS approval of the application tools used to collect the information needed to determine the eligibility of providers to participate in the PHP-CCP pool and their eligible uncompensated costs" by June 30, 2021. Grady Decl., Ex. C, at 37 of 74, ECF No. 29-1.

And it provides that "CMS and Texas will work collaboratively with the expectation of CMS approval of the protocol within 90 calendar days after it receives" Texas's submitted application tools. *Id.* That STC does not impose a mandatory deadline on CMS, and CMS regards these timelines as goals. Texas submitted the PHP-CCP "provider tools" to CMS on June 30, 2021, the deadline set forth in STC 39(b) for Texas to "revise, test, and obtain CMS approval" of those tools. CMS has not yet acted on that submission, and 90 days have not passed since Texas submitted those provider tools.

- 14. STC 39(b) also requires Texas to submit proposed rules and guidelines for it to claim federal funds for the PHP-CCP for the October 1, 2022 through September 30, 2023 demonstration year, referred to as "revised Attachment T," for CMS's approval by August 31, 2021. Texas also submitted the revised Attachment T to CMS on June 30, 2021. The provision that "CMS and Texas will work collaboratively with the expectation of CMS approval of the protocol within 90 calendar days" also applies to Texas's revised Attachment T. CMS has not yet acted on that submission and 90 days have not passed since Texas submitted that revised Attachment T.
- 15. STC 39(e) contains additional milestones that Texas must meet in implementing its PHP-CCP and sets forth financial penalties that CMS would apply if Texas fails to meet one or more of those milestones. Subsection (e) requires Texas to begin a state-level administrative rulemaking process related to its PHP-CCP no later than May 21, 2021; to submit revised PHP-CCP application tools to CMS by February 28, 2022; and to publish the final rule based on that administrative rulemaking process by July 31, 2022, with an effective date no later than September 30, 2022. Subsection (e) does not impose any obligations or deadlines on CMS.

16. Texas has also submitted quarterly payment reports, as required under STC 37(b), see Grady Decl., Ex. C, at 34 of 74, ECF No. 29-1, for the first and second quarters of 2021 on March 1, 2021, and May 27, 2021, respectively. Texas received acknowledgement from CMS's Performance Management Database and Analytics System (PMDA) for both of those submissions. CMS accepted Texas's second quarter report on PMDA on July 6, 2021, though it has not yet accepted Texas's first quarter report.

CMS'S APPROVAL OF TEXAS'S NON-EMERGENCY MEDICAL TRANSPORTATION (NEMT) AMENDMENT

17. On June 8, 2021, CMS approved an amendment to Texas's 1115 demonstration project (THTQIP) authorizing the provision of Non-Emergency Medical Transportation services. Grady Decl., Ex. F, at1, ECF No. 29-1. That amendment approval, including the length of time of that approval, is separate from and unrelated to the January 2021 extension approval at issue in this litigation.

OTHER DELIVERABLES RELATED TO MONITORING AND OVERSIGHT

- 18. The STCs also require Texas to submit other documents for monitoring and evaluation purposes. For example, under STC 74, Texas is required to submit quarterly monitoring reports within 60 days after the end of each demonstration quarter. Grady Decl., Ex. C, at 68–69 of 74, ECF No. 29-1. Texas submitted its monitoring report for the first quarter of 2021 on July 6, 2021, which includes January through March 2021, the first quarter after the January 15, 2021 extension approval. Prior to submitting that report, Texas requested, and CMS granted an extension of the June 1, 2021 deadline for filing that report. Texas received a notification from CMS's PMDA when it submitted that report.
- 19. STC 82 requires Texas to submit a Draft Evaluation Design within 180 days after the date CMS approves Texas's extension request. *Id.*, Ex. C, at 71 of 74, ECF No. 29-1. Texas

timely submitted that Draft Evaluation Design on July 14, 2021. And while the STCs do no
impose any deadline for CMS to respond or provide feedback on that Draft Evaluation Design,
see id., CMS has engaged with the state about that document. On July 22, 2021, CMS officials
attended a conference call with Texas officials related to the state's July 14, 2021 Draft
Evaluation Design. The purpose for that conference call was for Texas to provide a high-level
overview of its demonstration project as amended on January 15, 2021.

JUDITH CASH

Date