IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEXAS ALLIANCE FOR HOME CARE SERVICES, et al., Plaintiffs, v. KATHLEEN SEBELIUS, Secretary of the Department of Health and Human Services, et al., Defendants.	Civil Action No. 1:10cv747 (HHK)

REPLY IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS

Dated August 27, 2010

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INTRODUCTION

Two questions are at the heart of Plaintiffs' challenge to DMEPOS competitive bidding. First, did Defendants provide Plaintiffs with adequate notice and a meaningful opportunity to comment about how the Secretary will evaluate suppliers' financial viability in connection with a bid to participate in the DMEPOS program? In this regard, Defendants set forth in exhaustive detail in our opening brief the notice and comment rulemaking proceedings pertaining to financial standards. The notice of proposed rulemaking expressly stated that the Secretary would make supplier viability determinations based on suppliers' overall financial condition based on certain financial documentation suppliers would provide, and solicited and received suppliers' input on how best to conduct these evaluations. *See* Br. 8-11.[1] Second, have Defendants specified financial standards? Consistent with the notice of proposed rulemaking, the Secretary reaffirmed in the final rule that she intended to make financial viability determinations based on a broad, totality-of-the-circumstances approach, although the Secretary did modify what financial documents she would require bidders to provide in conjunction with DMEPOS applications to accommodate commenters' concerns that the proposed financial documentation would be overly burdensome to gather. Defendants furthermore specified the exact financial ratios from these financial documents that the Secretary will use to conduct her financial viability analysis — ratios that the Secretary released publicly approximately three years ago on an HHS website, following numerous public meetings and consultations with interested parties and members of the public. *Id.* at 7, 14-15 (financial ratios and PAOC meetings). Based on these judicially noticeable facts,

[1] Citations to Defendants' opening brief are in the form "Br. ___."

Defendants moved to dismiss Plaintiffs' Complaint on three grounds: (i) statutory preclusion of review; (ii) lack of Article III standing; and (iii) failure to state a claim upon which relief can be granted. *Id.* at 18-38.

Plaintiffs' opposition is not so much a response to Defendants' arguments as an attempt to reframe the discussion in a way that ignores those facts that are fatal to Plaintiffs' claims. With respect to the adequacy of the notice and comment rulemaking proceeding, Plaintiffs' analysis wrongly presumes their conclusion; namely, that the notice and comment rulemaking proceeding at issue was legally deficient. At no point do Plaintiffs address that the notice of proposed rulemaking expressly solicited comments on the financial standards the Secretary would apply, or that both the proposed and the final rule made clear that the Secretary would determine whether a supplier was sufficiently financially viable based on a comprehensive evaluation that considered the totality of a supplier's financial condition. Nor do Plaintiffs even acknowledge comments in the final rule addressing how the Secretary should make financial viability evaluations — comments that leave no doubt that others understood that the Secretary was seeking input on how to best evaluate suppliers' financial condition. To the extent Plaintiffs failed to comment, then, they have no one but themselves to blame.

Regarding the Secretary's specification of financial standards, Plaintiffs refuse to acknowledge that the Secretary has elected to evaluate suppliers' financial condition using a totality-of-the-circumstances approach, as the final rule expressly states. The Secretary has been similarly clear about how the financial ratios she will use in conducting her evaluations, publicly specifying on an HHS website the precise information that the Secretary will consider. And as to these financial ratios, Plaintiffs'

brief is entirely silent, pretending they do not exist and, in so doing, asking the Court to ignore their existence.

The nature of the parties' disagreement brings to mind the famous aphorism that everyone is entitled to his own opinion, but not his own facts. In this case, the parties have vastly different opinions about whether Article III jurisdiction is proper and whether Plaintiffs' Complaint states a valid cause of action. According to Plaintiffs, their opinions rest on "factual assertions of what was contained in the final and interim final rules, as well as the reasonable inference that . . . HHS has not divulged the required financial standards to DMEPOS suppliers or the public in any manner [and that the standards] do not in fact exist." Pls'. Br. at 26. The problem for Plaintiffs is that their opinions are premised on their "own facts" — facts that are demonstrably false. At its core, Plaintiffs' argument seems to be that this Court must blindly accept Plaintiffs' assertions that the Secretary's notice and comment rulemaking proceedings were inadequate, and that the Secretary has improperly failed to promulgate financial standards. This contravenes well-established principles of law regarding judicial notice. Plaintiffs seem to believe that in the name of notice pleading, they are entitled to mischaracterize or ignore outright the relevant portions of the Federal Register and other publicly available information. Not so. This Court is not bound to accept Plaintiffs' gloss on judicially noticeable facts.

What remains is a challenge to the degree of specificity of the Secretary's financial standards. Plaintiffs, however, expressly disavow making such a claim. Such a claim could not have succeeded in any event, as the MMA does not require the Secretary to specify the degree of particularity with which the Secretary must specify financial

standards. Nor is the Secretary required to specify through notice and comment rulemaking proceedings which financial ratios she will consider. The statute does not require the Secretary to "specify" financial standards in a particular manner, and the Secretary's specification of such ratios constitutes an "interpretive rule" under well-established principles of administrative law. For the separate and independent reasons below, Plaintiffs' Complaint must be dismissed.

ARGUMENT

I. THE MMA FORECLOSES JUDICIAL REVIEW OF PLAINTIFFS' CLAIMS

In our opening brief, Defendants explained that the Secretary had conducted notice and comment rulemaking proceedings regarding the financial standards the Secretary would use as part of her evaluation of DMEPOS bids. *See* Br. at 8-11; *accord* 71 Fed. Reg. 25,654, 25,675. In a section of the proposed rule titled "Financial Standards," the Secretary gave notice of the types of financial documentation she would require bidders to submit, as well as what financial information within this documentation would be most relevant to her financial viability analysis. In response to various comments she received, the Secretary modified the documents she would require bidders to submit so as not to unduly burden potential applicants. Br. at 9 (citing 72 Fed. Reg. 17,992, 18,037). The final rule also stated that the Request for Bid would specify what financial documents suppliers would have to provide, and gave examples of financial ratios that would be pertinent to the Secretary's analysis. 72 Fed. Reg. at 18,072. Accordingly, Defendants argued that "[t]here can be no question that Plaintiffs, like every other interested party, had ample opportunity to voice their opinions to CMS

about the . . . Secretary's financial evaluation process, during notice and comment rulemaking proceedings." Br. at 19.[2]

Plaintiffs concede, as they must, that HHS raised the subject of financial standards in the proposed rule, and invited comments. Pls'. Br. at 5. Plaintiffs also concede that "the notice of final rulemaking also discussed 'financial standards,'" correctly noting that the final rule identified "the financial documents required from bidders and the financial information in those documents that would be considered [by the Secretary in making financial viability determinations]." *Id.* Plaintiffs nonetheless contend that the Secretary has failed to provide "adequate notice and opportunity to comment on proposed rules." Pls'. Br. at 9; *id.* at 18 ("failure to provide sufficient notice and meaningful opportunity to comment"). Plaintiffs are wrong.

"The APA requires an agency to publish 'notice' of 'either the terms or substance of the proposed rule or a description of the subjects and issues involved,' in order to 'give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments,' and then, '[a]fter consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose." *American Radio Relay League, Inc. v. F.C.C.*, 524 F.3d 227,

[2] In light of this statement (and others), Plaintiffs' suggestion that "HHS never argues that Plaintiffs have failed to state a valid claim for relief with regard to inadequate notice and opportunity to comment" is frivolous. Pls'. Br. at 2, n.2. To the contrary, Defendants discussed the notice and comment rulemaking proceedings extensively in our opening brief to show that Plaintiffs' assertions of procedural inadequacy were demonstrably false. Br. at 8-11; s*ee also id.* at 29-30 ("Plaintiffs' assertion that they 'had to formulate their bids while being in the dark about the financial standards' is thus belied by judicially noticeable facts."). If, as Plaintiffs contend, Defendants have waived this argument, and were not asserting that notice and comment rulemaking proceedings were adequate, it is difficult to understand why Defendants would have bothered to include a section in our opening brief titled "Notice and Comment Rulemaking Proceedings."

236 (D.C. Cir. 2008) (citing 5 U.S.C. § 553(b)-(c)). There can be no question that the proposed rule adequately "describ[ed] the subjects and issues involved." In a section of the proposed rule titled "Financial Standards," the proposed rule stated in pertinent part that:

> [T]he [request for bid] will identify the specific information we will require to evaluate suppliers, which may include: a supplier's bank reference that reports general financial condition, credit history, insurance documentation, business capacity and line of credit to successfully fulfill the contract, net worth, and solvency. We welcome comments on the financial standards, in particular the most appropriate documents that will support these standards.
>
> We found that in the demonstration,[3] general financial condition, adequate financial ratios, positive credit history, adequate insurance documentation, adequate business capacity and line of credit, net worth, and solvency, were important considerations for evaluating financial stability.
>
> As we develop our methodology for financial standards, we will further consider which individual measures should be required so that we can obtain as much information as possible while minimizing the burden on bidding suppliers and the bid evaluation process.

71 Fed. Reg. 25,654, 25,675.

In light of these statements, numerous other parties unsurprisingly had no trouble discerning that the Secretary was — as the provision quoted above expressly states — seeking commenters' input on how the Secretary should make financial viability evaluations. The Secretary did receive numerous comments related to financial standards. *See generally* 72 Fed. Reg. 17,992, 18,037-18,039 (noting various comments on proposed rule relating to financial standards and agency responses to comments). The interim final rule notes that the Secretary received "several" comments suggesting that the Secretary use particular financial ratios in making financial viability determinations.

[3] *See* Br. at 3-11 (discussing DMEPOS demonstration projects).

Certain commenters suggested that the Secretary consider a supplier's debt to equity ratio; others suggested that EBITDA[4] would be more reliable as it is "more difficult to manipulate." *Id.* at 18,037. Still other commenters suggested using the quick ratio.[5] These comments — which address both the financial standards process generally as well as specific financial ratios the Secretary should consider — definitively undercuts Plaintiffs' assertion that they did not have meaningful opportunity to comment. *Cf. First American Discount Corp. v. Commodity Futures Trading Com'n*, 222 F.3d 1008, 1015 (D.C. Cir. 2000) ("The fact that others in First American's shoes . . . did comment on and indeed propose the guarantee option suggests that they, at least, regarded it as a logical outgrowth [of the proposed rule].").

In response, the Secretary stated in the final rule that she would use "appropriate financial ratios to evaluate suppliers," stressing that she would "be reviewing all financial information in the aggregate." 72 Fed. Reg. at 18,038. Plaintiffs may well disagree with the Secretary's totality-of-the-circumstances approach in which the Secretary makes financial viability determinations based on "overall financial soundness" rather than a "one [financial] ratio" in isolation. 72 Fed. Reg. at 18,038. However, that Plaintiffs disapprove of the Secretary's substantive decision does not mean that they were somehow denied notice of or an opportunity to comment on the Secretary's proposed course of action.[6]

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[4] EBITDA stands for earnings before interest, taxes, depreciation and amortization.
[5] The Secretary defined quick ratio in the final rule as (current assets – inventory) / current liabilities. *Id.* at 18,037.
[6] Plaintiffs correctly do not argue that the final rule on financial standards was not a "logical outgrowth" of the proposed rule. Regarding the Secretary's holistic approach to supplier financial evaluations, the proposed rule stated that in making viability determinations the Secretary might consider "a supplier's bank reference that reports

Under controlling precedent, then, it is clear that Plaintiffs' challenge to the adequacy of notice and comment rulemaking proceedings is without merit. This is why Defendants argued that Plaintiffs' challenge is "in reality an attack on the substance of the Secretary's financial standards." Br. at 19. Plaintiffs dismiss this argument in a footnote as "conclusory" and "clearly inaccurate," Pls'. Br. at 2, n.2, though they make no effort to explain why this is the case. Either unwilling or unable to meet Defendants' arguments head on, Plaintiffs criticize at length an argument that Defendants have *not* made. Plaintiffs assert that Congress could not have intended "to immunize HHS from having to comply with the notice and comment requirements of the APA, Medicare, and FOIA, and a statutory mandate such as the requirement that the Secretary specify financial standards." Pls'. Br. at 12. Defendants have never claimed otherwise. What Defendants are arguing, and what the Federal Register makes unmistakably clear, is that Defendants have conducted notice and comment rulemaking proceedings that afforded Plaintiffs' the requisite notice and opportunity to comment — an opportunity many others chose to take. *See generally* 72 Fed. Reg. 17,992, 18,037-18,039 (noting various comments on proposed rule relating to financial standards and agency responses). Throughout their brief, Plaintiffs wrongly presume their contrary conclusion; namely, that the Secretary's notice and comment proceedings were legally inadequate. *See, e.g.*, Pls'. Br. at 10 ("HHS . . . apparently contends that the plain wording of 'awarding of contracts' precludes judicial review for failure to comply with APA and Medicare

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general financial condition, credit history, insurance documentation, business capacity and line of credit to successfully fulfill the contract, net worth, and solvency." 71 Fed. Reg. 25,654, 25,675. The final rule reiterated this same information verbatim, and further stressed that the Secretary would "be reviewing all financial information in the aggregate and will not be basing our decision on one ratio but rather overall financial soundness." 72 Fed. Reg. at 18,038.

requirements for notice and comment on the specification of financial standards . . . . "). At no point do Plaintiffs ever attempt to reconcile their assertions of inadequacy with those portions of the Federal Register that conclusively belie their claims, nor do they cite any case law showing why the rulemaking proceedings at issue do not pass legal muster.

Once one moves past Plaintiffs' unsupported (and unsupportable) assertions regarding the purported absence of notice and the opportunity to comment, it is clear that Plaintiffs' "procedural injury" claims are nothing if not a challenge to substantive financial standards the Secretary has established. Again, Plaintiffs may disagree with the Secretary's "overall financial soundness" approach to financial viability determinations, 72 Fed. Reg. at 18,038, but Congress has committed that decision to the Secretary's unreviewable discretion. *See* 42 U.S.C. § 1395w-3(b)(11); Br. at 19 (no-review provision).

Plaintiffs rely chiefly on *Sharp Healthcare v. Leavitt*, 555 F. Supp. 2d 1121 (S.D. Cal. 2008) and *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986) to support their argument that judicial review is not foreclosed by statute. *Sharp* has been vacated, and therefore is no longer good law. *See Sharp Healthcare v. Leavitt*, 3:08cv170-w (S.D. Ca.) (Dkt. #53) (Order). Plaintiffs' citation to *Bowen* fares no better. In the absence of explicit statutory language foreclosing judicial review, the Supreme Court in *Bowen* declined to interpret the statute as a whole to preclude review. *Id.* at 678. What Plaintiffs neglect to mention is that unlike the MMA, and unlike the cases on which Defendants rely, the section of the Social Security Act at issue in *Bowen* did not have an express no-review provision. Plaintiffs' reliance on *Bowen* is therefore misplaced. More fundamentally, although Plaintiffs spill much ink in an effort to explain why the MMA's

"no-review" provision should not bar (true) claims of procedural injury, at no point do Plaintiffs argue that *substantive* challenges to the Secretary's financial standards are permitted. Because Plaintiffs' claims are in reality an impermissible attempt to interfere with the substance of the Secretary's financial evaluation process, they are foreclosed by statute. *See Carolina Med. Sales v. Leavitt,* 1:07cv1298 (D.D.C.) (concluding that the "broad, general" language Congress used in § 1395w-3(b)(11) "indicate a scheme to insulate the entire program from review") (Dkt. #30) (Mem. Op. at 13). Accordingly, the MMA forecloses judicial review of Plaintiffs' claims for relief.[7]

II. PLAINTIFFS LACK ARTICLE III STANDING

Plaintiffs' Complaint alleges that the Secretary's alleged "procedural failures . . . cause a distinct risk of harm to Plaintiffs' concrete Medicare DME supplier interests." Compl., ¶ 7. In our opening brief, Defendants explained that Plaintiffs' assertions of procedural injury were demonstrably false. Notwithstanding Plaintiffs' assertions to the contrary, we demonstrated that the Secretary did conduct adequate notice and comment rulemaking proceedings, subsequent to which she publicly specified the precise financial information on which she would rely in making financial viability determinations for DMEPOS competitive bidding. *See* Br. at 8-11 (notice and comment rulemaking proceedings); 14-15 (specification of financial standards).

[7] And even if Plaintiffs' claims were not precluded by statute, they would not be reviewable in any case because Congress established no criteria by which this Court could review whether the Secretary had adequately specified financial standards. Congress left the design and implementation of financial standards wholly to the Secretary. Because the MMA is "drawn in such broad terms that in a given case there is no law to apply" with respect to financial standards, the Secretary's specification of financial standards is therefore "committed to agency discretion." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971).

Defendants furthermore argued that even if this Court were to credit Plaintiffs' assertions of injury, Article III standing was nonetheless lacking because Plaintiffs had not demonstrated and could not demonstrate that the injuries they fear were caused by the Secretary's alleged "procedural failures," nor would any injury they might suffer be remedied by an order remedying these alleged procedural deficiencies. In this respect, Defendants explained that:

> [I]f Plaintiffs have submitted the requisite financial documentation as they claim, *see* Compl., ¶ 19, the Secretary will either accept or reject their bids to participate in the DMEPOS competitive bidding program based on, *inter alia*, her analysis of this documentation. No application will be turned down because of the Secretary's failure to articulate financial standards with a greater degree of specificity. And more specificity about the Secretary's evaluation process plainly cannot change a supplier's financial condition. . . . Plaintiffs' knowledge and understanding (or lack thereof) of how the Secretary would evaluate their financial submissions would be immaterial to the outcome of the bidding process. Even if the notice and comment procedures pertaining to financial standards were somehow deficient, then, Plaintiffs cannot show that it is "substantially probable" that these alleged deficiencies would cause Plaintiffs *any* injury, let alone "the essential injury to [Plaintiffs'] own interest."

Br. 28-29 (citing *County of Delaware, Pennsylvania v. Dep't. of Transp.*, 554 F.3d 143, 147 (D.C. Cir. 2009).[8]

Plaintiffs respond to none of this, nor could they. In lieu of any response, Plaintiffs seek refuge in notice pleading standards, arguing that "[a]t the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice." Pls'. Br. at 20 (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). To

[8] This argument credits Plaintiffs' assertion that they "submitted the required financial documentation in 2009." Pls'. Br. at 6; *accord* Compl., ¶ 19. If this assertion proves incorrect, however, and Plaintiffs have not submitted the requisite financial documentation, Defendants argued that Plaintiffs' "injury (namely, their eventual, inevitable non-selection to be a participating DMEPOS contract supplier) would be a self-inflicted wound not attributable to the Secretary." Br. at 27. Plaintiffs correctly do not contest that standing would be absent under those circumstances.

begin with, the "general factual allegations" on which Plaintiffs rely are not "factual allegations" at all — they are *legal* assertions and characterizations of judicially noticeable documents (*e.g.*, the proposed and final rules) that speak for themselves. Plaintiffs' repeated claims that the Secretary is evaluating DMEPOS bids using "unspecified and procedurally invalid rules," *see, e.g.*, Pls'. Br. at 21, are precisely the sort of "conclusory legal assertion[s] that the Court need not accept as true in resolving a motion to dismiss." *King & King, Chartered, v. Harbert Intern., Inc.*, 436 F. Supp. 2d 3, 16 n.24 (D.D.C. 2006). Nor is the Court "bound to accept as true a legal conclusion couched as a factual allegation." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). Plaintiffs' assertion, for example, that they "face the distinct and imminent risk that they will not be offered a DMEPOS supplier contract because the [sic] do not meet undisclosed and invalid financial standards," Pls'. Br. at 20, is therefore entitled to no deference whatsoever, as that statement wrongly presumes that the Secretary's financial standards are unlawful. And where, as here, the "facts" on which Plaintiffs would rely to demonstrate injury are "essentially fictitious" or "patently insubstantial," *compare* Br. 8-11, 14-15 *with* Pls'. Br. at 20 (citing Complaint), "[a] complaint may be dismissed on jurisdictional grounds," as the complaint "present[s] no federal question suitable for decision." *Tooley v. Napolitano*, 586 F.3d 1006, 1009 (D.C. Cir. 2009) (citing *Best v. Kelly*, 39 F.3d 328, 330 (D.C. Cir. 1994)).[9]

[9] As Plaintiffs correctly recognize, this Court "may consider such materials outside the pleadings as it deems appropriate to resolve the question of whether it has jurisdiction." Pls'. Br. at 20 (citing cases).

But even assuming *arguendo* that Plaintiffs had adequately alleged a procedural injury in fact at the pleading stage, they have utterly failed to demonstrate how the Secretary's purported deficiencies (namely, providing inadequate opportunity for notice and comment or failure to specify financial standards) are causally related to the Secretary's substantive determination regarding Plaintiffs' DMEPOS supplier bids. Indeed, Plaintiffs do not even try to explain how their asserted injury — which they characterize as "the 'distinct risk' of not obtaining a contract offer" — could have been caused by these procedural inadequacies, or how remedying such deficiencies could make any conceivable difference to Plaintiffs' chances of "obtaining a contract offer." Pls'. Br. at 22. Ignoring both causation and redressability, Plaintiffs essentially seek to reduce "[t]he irreducible constitutional minimum of standing" to the question of whether Plaintiffs have suffered injury. *Steel Co. v. Citizens for a Better Env't.*, 523 U.S. 83, 103 (1998) (citation omitted). This attempt to collapse the standing inquiry contravenes bedrock principles of Article III jurisdiction. The "*triad* of injury in fact, causation, *and* redressability" constitute "an indispensable part of the [Plaintiffs'] case," and Plaintiffs therefore bear the burden to demonstrate "each element." *Steel Co.*, 523 U.S. at 103 (emphasis added); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). Indeed, the D.C. Circuit has expressly rejected attempts to merge a "'procedural right' and the 'concrete interest' in a procedural-rights case," holding that "[t]he two things are not one and the same." *Center for Law and Educ. v. Department of Educ.*, 396 F.3d 1152, 1159 (D.C. Cir. 2005).

It is no answer to assert, as Plaintiffs erroneously do, that the standing inquiry is "more relaxed" in the procedural injury context. Pls'. Br. at 22-23 (citing *Lujan*). The

D.C. Circuit has held precisely the opposite, *i.e.*, that the standing inquiry is *not* relaxed as to either injury or causation in the procedural injury context. *Center for Law and Educ.*, 396 F.3d at 1157 ("Where plaintiffs allege injury resulting from violation of a procedural right afforded to them by statute and designed to protect their threatened concrete interest, the courts relax — while not wholly eliminating — the issues of imminence and redressability, *but not the issues of injury in fact or causation*.") (emphasis added). And furthermore, "relaxed" is one thing; non-existent is quite another, as this Court has correctly recognized. *See Friends of Animals v. Salazar*, 626 F. Supp. 2d 102, 115 n.6 (D.D.C. 2009) (also citing *Lujan*) (Kennedy, J.) ("While the causation and redressibility requirements are relaxed for procedural injuries, they are not eviscerated.").[10] Under Plaintiffs' novel and unsupported theory of standing, causation and redressability would be meaningless. Any accredited bidder who applied to be a DMEPOS supplier and who provided the requisite financial documentation would have standing to challenge the Secretary's design and implementation of the DMEPOS program, just as Plaintiffs here have. That means that even suppliers whose bids are ultimately accepted and who will be awarded DMEPOS supplier contracts would nonetheless be entitled to file a lawsuit to halt the entire DMEPOS program because of the same alleged procedural defects of which Plaintiffs complain. After all, even these winning bidders would have been afforded no more notice than Plaintiffs received, nor been given any more meaningful opportunity to comment. *Cf.* Pls'. Br. at 18. And like Plaintiffs, every winning bidder would have had to submit its bid while being in the same

[10] *But see Center for Law and Educ.*, 396 F.3d at 1157 (causation inquiry not relaxed for procedural injury claims).

"dark about the financial standards that would be applied to their businesses," Compl., ¶ 19, subject to those same financial standards that the Secretary has hidden in plain sight on a public website. *See* Br. at 14-15 and n.13.

That cannot be and is not the law. As the D.C. Circuit has recognized in the procedural injury context, "it is not enough to show that the agency omitted some procedural requirement"; Plaintiffs "must also show that it is substantially probable that the procedural breach will cause the essential injury to [Plaintiffs'] own interest." *County of Delaware*, 554 F.3d at 147 (internal quotations omitted) (dismissing procedural injury claim for lack of causation and redressability). For the reasons stated previously, Plaintiffs have failed to carry their burden to show that any of these three essential components of Article III standing is present, let alone all of them. Plaintiffs' assertions of injury are plainly false. Furthermore, Plaintiffs have failed to show how any risk they run "of not obtaining a contract offer" could have been caused by the purported procedural defects about which they complain, or how such risk would be reduced or eliminated by the relief Plaintiffs seek.[11] For each of these separate and independent reasons, dismissal is required.

[11] The relief Plaintiffs seek confirms that jurisdiction is lacking. According to Plaintiffs, "the remedy for [Defendants' alleged failure to publicly specify financial standards] is to require either publication of the financial standards, as well as their basis, or production of those standards to Plaintiffs." Pls'. Br. at 18. Even making the exceedingly dubious assumption that Plaintiffs somehow remained unaware of the Secretary's totality-of-the-circumstances financial standards — which the Secretary published in the interim final rule and further elucidated on a publicly available HHS website — defendants produced these standards to Plaintiffs in our opening brief. *See* Br. at 14-15. Because Plaintiffs now inarguably have the very remedy they request, their claims for relief are now moot (assuming for argument's sake that they were ever live). *Safir v. Dole*, 718 F.2d 475, 481 (D.C. Cir. 1983) ("Standing, since it goes to the very power of the court to act, must exist at all stages of the proceeding, and not merely when the action is initiated or during an initial appeal.").

III. PLAINTIFFS HAVE FAILED TO STATE A CLAIM ON WHICH RELIEF CAN BE GRANTED

In our opening brief, Defendants argued that Plaintiffs' challenge to the specificity of the Secretary's financial standards failed to state a claim on which relief could be granted. Because Congress did not require the Secretary to specify financial standards at a particular level of detail, Defendants argued that HHS "is entitled to broad deference in picking the suitable level [of regulatory detail]." Br. at 30 (citing *Cement Kiln Recycling Coalition v. EPA*, 493 F.3d 207, 217 (D.C. Cir. 2007). Defendants further argued that the Secretary's decision not to release either the precise methodology she would use to make financial viability determinations or the financial viability cutoff was reasonable. This was so, we explained, because "the Secretary must be free to modify the competitive bidding program to account for the teachings of experience," and "requiring the Secretary to publish [her] precise methodology by which she will evaluate the inputs gleaned from supplier documentation and then faithfully adhere to that methodology (at least absent further rounds of notice and comment rulemaking) would wrongly deprive the Secretary of the flexibility the statute makes clear that she has to tailor the competitive bidding process on an ongoing basis." Br. at 32-33. Furthermore, requiring the Secretary to release her specific methodology or financial viability cutoff would undermine Congress' stated purpose in combating waste, fraud, and abuse in the Medicare procurement and reimbursement process. *Id.* at 33-34. Because the Secretary's chosen level of specificity is reasonable under binding precedent, *see generally id.* at 30-32 and n.23, Defendants demonstrated in our opening brief that Plaintiffs' challenge that the Secretary's financial standards are insufficiently specific failed to state a claim upon which relief could be granted because the statute indentifies no basis for demanding what

level of specificity is, by Plaintiffs' terms, sufficiently specific. *See generally id.* at 29-38.

Plaintiffs expressly decline to respond to any of these arguments, asserting that "[i]n arguing for dismissal of the Complaint, HHS attempts to argue not the insufficiency of the Complaint, but the merits of the issue regarding compliance with the statutory mandate . . . to specify financial standards." Pls'. Br. at 27. According to Plaintiffs, "this is not appropriate in a motion to dismiss, which is supposed to address only whether the Complaint is sufficient to put HHS on 'short and plain notice' as to the claims for relief being made." Plaintiffs consequently proclaim that they "do not have to, and will not respond to those arguments at his [sic] point in the proceedings." *Id.*

Citing various case law on notice pleading, Plaintiffs argue that they have alleged sufficient facts to survive a motion to dismiss. *See generally* Pls'. Br. at 25-27. All of Plaintiffs' "facts" pertain to either (i) the Secretary's alleged failure to conduct proper notice and comment rulemaking proceedings; (ii) the Secretary's alleged failure to specify the financial standards she will use to evaluate DMEPOS bids; or (iii) Plaintiffs' characterizations of what was said in the notice of proposed rulemaking and final rule. The problem for Plaintiffs is that these purported "facts" are demonstrably false, as Defendants have repeatedly explained. *See* Br. 8-11 (notice and comment rulemaking proceedings); 14-15 (financial standards); *supra* at 4-6. "In determining whether a complaint states a claim, the court may consider the facts alleged in the complaint, documents attached thereto or incorporated therein, and *matters of which it may take judicial notice.*" *Stewart v. Nat'l. Educ. Ass'n*, 471 F.3d 169, 173 (D.C. Cir. 2006)

(emphasis added).[12] This Court should take judicial notice of the relevant portions of the proposed and final rules published in the Federal Register as well as the Secretary's public promulgation of more specific criteria on an HHS website that will guide the Secretary's evaluation of the applicants, which collectively make clear that Plaintiffs' Complaint fails to state a cognizable claim for relief.[13]

Having disclaimed any intention of responding to Defendants' arguments regarding the Secretary's specification of financial standards, Plaintiffs nonetheless proceed to point out that Defendants have misconstrued Plaintiffs' argument regarding the promulgation of financial standards. In this regard, Plaintiffs state that "[t]o be clear, the Complaint does not allege, as HHS suggests repeatedly, that HHS promulgated standards that were not sufficiently precise; the Complaint alleges that HHS has not properly proposed for comment or promulgated any standards at all." Pls'. Br. at 17, n.14. If, as Plaintiffs claim, they are not challenging the degree of specificity with which the Secretary has promulgated financial standards, but rather whether she provided notice and opportunity for comment or ultimately included in the final rule *any* financial standards whatsoever, their decision to ignore Defendants' specificity arguments makes somewhat more sense. But this clarification of Plaintiffs' claim is also its death knell.

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[12] Indeed, under Plaintiffs' theory of notice pleading, it is hard to see how a Complaint could ever be dismissed at the pleading stage, as even demonstrably false factual allegations could sustain a "well-pleaded complaint." Plaintiffs unsurprisingly offer no legal authority for such a proposition.

[13] Plaintiffs' claim based on the Freedom of Information Act is similarly baseless. 5 U.S.C. § 552(a)(1) states only that an agency cannot enforce "a matter required to be published in the Federal Register and not so published," "[e]xcept to the extent that a person has actual and timely notice of the terms thereof." Plaintiffs here plainly know or should know how the Secretary will make financial viability determinations based on the information provided in proposed and final rules, as well as on an HHS website for DME suppliers.

Defendants have previously addressed Plaintiffs' argument regarding notice and comment, and need not restate here yet again the reasons why Plaintiffs' claims related to the allegedly deficient notice and comment rulemaking are invalid.[14] A reading of the proposed and final rules reveals that Plaintiffs' assertion is baseless. Their assertion that the Secretary has failed to promulgate any financial standards "at all" is also wrong. In the final rule, the Secretary reiterated that she would use "appropriate financial ratios to evaluate suppliers," stressing that she would "be reviewing all financial information in the aggregate." 72 Fed. Reg. at 18,038. The Secretary gave in the final rule examples of relevant information she might consider in evaluating suppliers, including a supplier's debt to equity ratio as well as "a financial credit worthiness score from a reputable financial services company." *Id.* In our opening brief, Defendants also explained that the Secretary had publicly specified the precise financial information she would consider in making financial viability determinations, maintaining this information on a website that remains publicly available to this day. Br. at 14-15. Plaintiffs inexplicably ignore these facts, persisting in the increasingly ridiculous fiction that they remain unaware of the financial standards the Secretary will apply. *See* Pls'. Br. at 25 (requesting that Defendants "divulge to Plaintiffs the specific financial standards it would apply").[15]

[14] Plaintiffs' suggestion that Defendants' "supporting Memorandum does not challenge under FRCP 12(b)(6), with any legal argument, that Plaintiffs have failed to state claims upon which relief can be granted . . . regarding failure to provide adequate notice and opportunity to comment on the required specification of 'financial standards'" is disingenuous. Pls'. Br. at 2. Defendants went to great length to demonstrate that all of Plaintiffs claims were premised on factual assertions that were demonstrably false, and therefore should be dismissed. Br. at 8-11; 14-15, *supra* at 4-6.

[15] Again, this cannot be construed as a request for the Secretary to disclose either her specific methodology or financial viability cutoff, as Plaintiffs expressly disclaim arguing that the Secretary's financial standards were insufficiently precise. *See* Pls'. Br. at 17, n.14.

Nor do Plaintiffs address Defendants' argument that in amending the MMA in MIPPA, Congress ratified the Secretary's design and implementation of the financial evaluation process of the DMEPOS competitive bidding program in all respects material to this case. In our opening brief, Defendants explained that although Congress was clearly aware of complaints about the rules regarding the competitive bidding program—including the claim of insufficient specificity of financial standards — it declined to amend the MMA provisions in the manner Plaintiffs evidently would have liked to require more hard and fast standards and also declined to delay the implementation of the DME competitive bidding program beyond the rebid. Br. at 35-38. Consequently, Defendants argued, this Court should decline to constructively amend the statute to require the Secretary to publish her specific financial methodology or financial viability cutoff score (as distinguished from the financial documentation and financial ratios, which are already public) — changes Congress itself did not see fit to make.

Plaintiffs retort that "[a]gencies cannot ignore Congressional mandates simply because they believe the mandate is not a good idea," observing that federal law provides "severe penalties" for fraud. Pls'. Br. at 26-27 n.18. But this misses the entire point. In declining to publish in the proposed or final rules a specific financial methodology or financial viability cutoff score, the Secretary was not "ignor[ing a] Congressional mandate[]"; rather, the Secretary was acting consistent with the discretion Congress afforded her under the statute, and that her actions were subsequently ratified. Were this not the case, and Congress had indeed been dissatisfied with the manner in which the Secretary had designed or implemented the financial standards aspect of the DMEPOS program, after reviewing the program during the moratorium period Congress would

have amended the MMA to require the disclosures Plaintiffs claim the Secretary was statutorily obligated to make. *See* Br. at 36-37 ("If, as Plaintiffs claim, the Secretary's financial evaluation process were insufficiently transparent, or otherwise operated in a manner Congress deemed improper, it stands to reasons that Congress would have corrected such ostensible flaws when it amended the MMA via MIPPA. That Congress did not correct the supposed 'defects' that Plaintiffs ask this Court to declare unlawful suggests that, in Congress' view, the Secretary's financial evaluation process was not defective in the first place."). It bears repeating that Congress took a hard look at the competitive bidding program as designed by the Secretary. For two years, Congress placed a moratorium on competitive bidding to evaluate complaints about the program. After this extended evaluation, and as material here, Congress declined to make any changes to the Secretary's design and implementation of the financial standards aspect of competitive bidding. *See* Br. at 37.

To the extent that Plaintiffs are arguing that the MMA requires the Secretary to promulgate financial standards in a particular manner, the definitive answer to this is that the statute mandates no such thing. The MMA merely sets various parameters limiting the universe of suppliers eligible to receive Medicare supplier contracts, including the requirement that suppliers meet "financial standards specified by the Secretary . . . ." 42 U.S.C. § 1395w-3(b)(2)(A)(ii). The MMA says nothing about the manner or context in which the Secretary must "specif[y]" financial standards.[16] Indeed, the Secretary makes

[16] Plaintiffs imply that the rulemaking proceeding was invalid because the request for bids — which identifies what financial documentation bidders must provide — "was not published as part of the notice of proposed rulemaking." Pls'. Br. at 5, n.7. Plaintiffs are mistaken: notice and comment proceedings are sufficient if they provide a "description of the subjects and issues involved." *American Radio Relay League, Inc. v. F.C.C.*, 524

numerous DMEPOS announcements via public websites, including DMEPOS fee schedule updates, claims processing instructions, and the interpretive guidelines used to evaluate providers' compliance with requirements for participation.

Nor is the Secretary required to specify through notice and comment rulemaking proceedings which financial ratios she will use to evaluate suppliers' financial viability. Notice and comment rulemaking proceedings are required for "substantive rules," but not interpretive rules. Unlike substantive rules, which "grant rights, impose obligations, or effect a change in existing policy[,]" "interpretive rules are those that merely clarify or explain existing laws or regulations." *National Medical Enterprises, Inc. v. Shalala*, 43 F.3d 691, 697 (D.C. Cir. 1995). Otherwise, and contrary to Congress' stated desire and as well as the public interest, the competitive bidding program would be hopelessly bogged down in unending notice and comment rulemaking proceedings, given the thousands of decisions the Secretary must make in designing and implementing competitive bidding. The Secretary's announcement of which financial ratios she would consider is not a "substantive" rule requiring notice and comment, as this announcement does not "put[] a stamp of agency approval or disapproval on a given type of behavior." *Chamber of Commerce of U.S. v. U.S. Dep't. of Labor*, 174 F.3d 206, 211 (D.C. Cir. 1999) (quotations omitted). By specifying those financial ratios she would consider, the Secretary merely clarified what information would be most relevant to her analysis — which comprehensive approach *was* announced via notice and comment rulemaking proceedings. Accordingly, to the extent Plaintiffs are arguing that the Secretary is

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F.3d 227, 236 (D.C. Cir. 2008) (citing 5 U.S.C. § 553(b)-(c)). Even Plaintiffs concede that the proposed rule does this. *See* Pls'. Br. at 5 (notice of proposed rulemaking "raised the subject of 'financial standards'").

obligated to specify which financial ratios she will consider within the context of notice and comment rulemaking proceedings, their Complaint fails as a matter of law.

A final comment is in order. For more than seven years, the Secretary has, at Congress' direction, worked to design and implement a program to allow Medicare beneficiaries to obtain DMEPOS products at competitive prices while reducing or eliminating the waste, fraud, and abuse that impelled Congress to mandate a competitive bidding regime in the first place. Plaintiffs nonetheless ask this Court to vacate the interim final rule and begin the notice and comment rulemaking proceedings and the contract award process anew. *See* Compl., Prayer For Relief, ¶ 4, Pls'. Br. at 4, n.5 & 28, n.19. In making this request, Plaintiffs seek to turn these years of effort against the Secretary, cavalierly asserting that "the delay would be small compared to those [delays] that have already taken place," as if the mere fact of past delays somehow justifies future ones. Pls'. Br. at 4, n.5.[17] By requiring a rebid in 2009 in MIPPA, Congress has indicated that no further delay is in order.

Plaintiffs are scornful of the financial costs that the delay they seek would impose on Medicare. According to CMS estimates, the DMEPOS competitive bidding program can expect to realize $17 billion in savings over ten years[18] — savings Plaintiffs blithely dismiss as "only a very small part of the Medicare budget." Pls'. Br. at 4, n.5. That point merits no further discussion because the Medicare program consists of many components

[17] Further delay would also prejudice bidders, as they would have to bid again.

[18] "Medicare To Save Average Of 32 Percent For Some Medical Equipment And Supplies In Selected Areas," *available at* http://www.cms.gov/apps/media/press/release.asp?Counter=3779&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=false&cboOrder=date

and covers many diverse services. While no one service makes up most of the total Medicare budget, Congress has shown concerns about excess costs in many areas and has chosen to counter burgeoning and often wasteful DME payments by requiring competitive bidding. It is not for Plaintiffs to second-guess this choice.

Although the do-over Plaintiffs seek is ostensibly about giving Plaintiffs the opportunity to express their views on the design of the Secretary's financial standards and informing them how the Secretary will make financial viability determinations, it should by now be evident that Plaintiffs' professed reasons for initiating this litigation cannot be taken seriously. The reality is that this lawsuit is, at bottom, an effort to make sure that business as usual continues, notwithstanding Congress' considered judgment that it should not. DMEOPS opponents tried and failed to convince Congress to scrap the competitive bidding program, and Plaintiffs now turn to this Court for the relief they were evidently unable to obtain from the democratically elected branches of government. Simply put, this Court should not countenance Plaintiffs' efforts to derail Congress' reform initiatives that are almost a decade in the making.

CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss should be granted, and Plaintiffs' Complaint should be dismissed.

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Washington, D.C.

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