

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

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,

Plaintiffs,

–v–

THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES, *et al.*,

Defendants.

Case No. 18-2112 (JDB)

**MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION
TO DISMISS AND REPLY MEMORANDUM IN SUPPORT OF
PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

Dated: November 21, 2018

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INTRODUCTION

In the mid-2000s, the Office of the Inspector General of the Department of Health and Human Services (“HHS”) issued a series of reports identifying various shortcomings of the 340B Drug Pricing Program, including the absence of a clear methodology for calculating ceiling prices, the secretive nature of ceiling prices, and the absence of enforcement by HHS. *See* Mem. In Supp. of Pls.’ Mot. for Summ. J., ECF No. 2-1 (“Pls.’ S.J. Mem.”) at 3-6. That drumbeat of criticism led Congress to address each of those problems. To improve the accuracy of ceiling prices, Congress required HHS to develop a “system to . . . verify the accuracy of ceiling prices calculated by manufacturers,” including to enact “precisely defined standards and methodology for the calculation of ceiling prices.” 42 U.S.C § 256b (d)(1)(B)(i). To improve transparency, Congress required that 340B providers be given online access to “the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary.” *Id.* § 256b(d)(1)(B)(iii). And to improve compliance, Congress required HHS to impose “sanctions in the form of civil monetary penalties” against drug companies that “knowingly and intentionally” overcharge 340B providers. *Id.* § 256b(d)(1)(A).

Each of those statutory mandates was designed to protect 340B providers from the problems that had plagued them – and that continue to plague them because HHS has repeatedly delayed implementing the Final 340B Rule, 82 Fed. Reg. 1,210 (January 5, 2017). Those harms also give Plaintiffs standing to challenge HHS’s impermissible delays in complying with Congress’s mandate. Meanwhile, on the merits, Defendants HHS and the Secretary of HHS have apparently concluded that their repeated, extended delays were unwarranted, and thus they have declined to defend them.

The Court should deny Defendants' motion to dismiss, grant judgment for Plaintiffs, and issue an order directing HHS to make the Final 340B rule effective by January 1, 2019, and to post the ceiling prices for 340B drugs by April 1, 2019, at the latest.

ARGUMENT

Standing under Article III requires that "(1) [a plaintiff] has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc. v. Laidlaw Enviro. Servs. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000). Plaintiffs have suffered several types of injury, as discussed in section I.A below. Defendants do not dispute that Plaintiffs' injuries are "fairly traceable to the challenged action of the defendant[s]." Rather, they argue that (1) Plaintiffs' injuries would only be sufficient if Plaintiffs could identify particular instances in which the Hospital Plaintiffs or other 340B providers have been overcharged for 340B drugs, and (2) even if those injuries are cognizable under Article III, the injuries would not be guaranteed to be redressed because drug companies could theoretically choose to withdraw their drugs from the entire 340B and Medicaid markets nationwide.

The Hospital and Association Plaintiffs have suffered multiple independent forms of injury, any of which would be sufficient, and each of which would be redressed by ordering Defendants to comply with their statutory mandate and implement the Final 340B Rule.

I. THE HOSPITAL PLAINTIFFS HAVE STANDING TO CHALLENGE DEFENDANTS' ARBITRARY, CAPRICIOUS AND UNREASONABLE DELAY.

A. The Delay Has Injured the Hospital Plaintiffs and the Association Plaintiffs' Members.

The Hospital Plaintiffs, and other members of the Association Plaintiffs, have been injured in three independent ways, any of which would be sufficient to establish an injury in fact.

First, they have suffered an “informational injury.” “[A] plaintiff suffers an ‘injury in fact’ when the plaintiff fails to obtain information which must be publicly disclosed pursuant to a statute.” *Fed. Election Comm’n v. Akins*, 524 U.S. 11, 21 (1998). “[T]he existence and scope of an injury for informational standing purposes is defined by Congress: a plaintiff seeking to demonstrate that it has informational standing generally ‘need not allege any additional harm beyond the one Congress has identified.’” *Friends of Animals v. Jewell*, 828 F.3d 989, 992 (D.C. Cir. 2016) (quoting *Spokeo, Inc. v. Robins*, 578 U.S. ___, 136 S. Ct. 1540, 1549 (2016)). *See also, e.g., Sargeant v. Dixon*, 130 F.3d 1067, 1070 (D.C. Cir. 1997) (“The receipt of information is a tangible benefit the denial of which constitutes an injury.”).

Thus, to establish a “concrete and particularized informational injury,” a plaintiff need only show that “(1) it has been deprived of information that, on its interpretation, a statute requires the government or a third party to disclose to it, and (2) it suffers, by being denied access to that information, the type of harm Congress sought to prevent by requiring disclosure.” *Id.*; *see also Public Citizen v. Dept. of Justice*, 491 U.S. 440, 449 (1989) (advocacy organizations’ inability to obtain information subject to disclosure under the Federal Advisory Committee Act “constitutes a sufficiently distinct injury to provide standing to sue”); *Public Citizen v. F.T.C.*, 869 F.2d 1541, 1548 (D.C. Cir. 1989) (“An infringement of an individual’s statutory right to receive information has sufficed in other contexts to endow parties with

standing.”). Special weight is given to Congressional determinations that access to particular information is valuable and thus that lack of access constitutes injury. *Public Citizen*, 869 F.2d at 1549.

Plaintiffs here easily satisfy both requirements of informational injury because “a statute requires the government or a third party to disclose” the information at issue. *Friends of Animals*, 828 F.3d at 992. The 2010 amendments required HHS to grant 340B providers “access” to “the applicable ceiling prices . . . as calculated and verified by the Secretary.” *Id.* § 256b(d)(1)(B)(iii). And the harm caused by keeping 340B providers in the dark about ceiling prices is precisely “the type of harm Congress sought to prevent by requiring disclosure.” 828 F.3d at 992. Congress was explicit that it was mandating disclosure of ceiling prices in order to “improve[] . . . compliance by manufacturers,” and thereby “to prevent” drug companies from committing “violations of the discounted pricing requirements” such as “overcharg[ing]” 340B providers. 42 U.S.C § 256b(d)(1)(A). As demonstrated by their declarations, Plaintiffs would use the new information on ceiling prices to monitor section 340B pricing and to insure that they are receiving the discounts to which they are entitled. *See* Ex. 1 (Declaration of Molly Smith, American Hospital Association) at ¶ 5; Ex. 2 (Declaration of Dr. Bruce Siegel, America’s Essential Hospitals) at ¶ 5; Ex. 3 (Declaration of Dr. Janis Orłowski, Association of American Medical Colleges) at ¶ 5; Ex. 4 (Declaration of Maureen Testoni, 340B Health) at ¶ 5; Ex. 5 (Declaration of Matt Perry, Genesis Healthcare System) at ¶ 4; Ex. 6 (Declaration of Benjamin Anderson, Kearny County Hospital) at ¶ 4; Ex. 7 (Declaration of Jonathan Reynolds, Rutland Regional Medical Center) at ¶ 4. That benefit is sufficient to confer standing.

The *Akins* case illustrates why Plaintiffs need not prove anything more than that. In *Akins*, voters sued to challenge a Federal Election Commission finding that the American Israel

Political Action Committee (“AIPAC”) was not a “political committee,” a ruling that exempted AIPAC from requirements to disclose, for example, its donors and the identity of candidates for political office to which it contributed. 524 U.S. at 21. The voters argued they were harmed because without that information, they were hampered in their ability to “evaluate candidates for public office” and to “evaluate the role that AIPAC’s financial assistance might play in a specific election.” *Id.* The Supreme Court held that was sufficient to show an “informational injury” because there was “no reason to doubt” the voters’ “claim” that having the information “would help them” achieve those objectives – precisely the transparency-related purpose the applicable statute (the Federal Election Campaign Act) aimed to achieve. *Id.* Indeed, if anything, the value of ceiling price data to 340B providers is more direct and concrete than the value of the AIPAC information was to the *Akins* plaintiffs. Not only would disclosure of ceiling prices deter drug companies from overcharging 340B providers (sunshine being the best disinfectant), but it also would make it possible for 340B providers to determine whether they have in fact been overcharged and then, if so, to seek refunds for any such overcharges.

Defendants argue Plaintiffs’ informational injury is insufficient because “Congress did not intend for the pricing information to be an end in and of itself” but rather to “protect [340B providers] from being overcharged” – a premise from which Defendants argue that Plaintiffs “must allege that they have been overcharged” and that any such overcharges were “because they have been deprived of the ceiling-price information.” Mem. in Opp. To Pls.’ Mot. for Summ. J. & In Supp. Of Defs.’ Mot. to Dismiss, ECF No. 25 (Nov. 13, 2018) (“Defs.’ Mem.”), at 9, 10 (emphasis added). Defendants even seem to suggest that Plaintiffs must identify particular drugs that were sold to particular hospitals on particular dates at prices that exceeded their ceiling

price. *Id.* at 8 (arguing that Plaintiffs must “identify an injured member *by name*” and identify how they were “overcharged”).

Defendants misconstrue the nature of Plaintiffs’ informational injury. Plaintiffs do not contend that Congress intended for disclosure of ceiling prices to be “an end in and of itself.” *Id.* Congress surely did perceive as intolerable the fact that drug companies could shroud in secrecy the data necessary for 340B providers to know whether they were being overcharged. But it mandated disclosure not for its own sake, but rather to increase accountability, to deter drug companies from overcharging 340B providers, and to give 340B providers the information necessary to prevent and remedy overcharges – such as by reporting overcharges to HHS’s Inspector General for investigation and imposition of civil monetary penalties. The fact that disclosure of ceiling price data itself accomplishes those ends does not make disclosure “an end in and of itself.” *Id.*

Insofar as Defendants suggest that Plaintiffs must identify particular overcharges to particular hospitals on particular dates, the argument is simply absurd. Plaintiffs’ informational injury flows from ceiling prices having been hidden from them. To suggest that Plaintiffs could only sue to gain access to ceiling prices by proving that the prices they paid exceeded these secret ceiling prices would be the definition of a Catch-22. *Akins* also demonstrates that Defendants’ proposed test is far stricter than the law requires. In *Akins*, the Court did not require the plaintiff voters to identify candidates who had received AIPAC funding whom the voters supported but whom they would *not* have supported if the voters had *also* had a list of AIPAC’s donors. The imposition of any such requirement here would be equally improper.

In short, Plaintiffs have suffered an informational injury by Defendants’ extended delays in implementing the Final 340B Rule.

Second, independent of the harm to 340B providers caused by their lack of access to ceiling data, they have been harmed by the delayed implementation of the methodology improvements that Congress required. Congress directed HHS to “[d]evelop[] and publish[] . . . precisely defined standards and methodology for the calculation of ceiling prices.” 42 U.S.C. §§ 256b(d)(1)(B)(i)(I); 256b(d)(1)(A). Defendants argue that having 340B ceiling prices calculated under existing methodologies does not constitute an injury in fact because “[a]n inaccurate calculation is not necessarily a harmful one.” Defs.’ Mem. at 7 (citing *Spokeo*, 136 S. Ct. at 1550). But Congress explicitly recognized that hospitals are more likely to be overcharged in the absence of precise standards. *See* 42 U.S.C. § 256b(d)(1)(A) (stating that more “precisely defined standards and methodology” are necessary to “prevent overcharges”). Courts grant significant deference to Congressional findings that particular rules are necessary to remedy particular wrongs. *See, e.g., Public Citizen v. F.T.C.*, 869 F.2d at 1549 (giving “great weight” to the “congressional determination” that a “comprehensive approach” to tobacco warnings “is necessary to protect young people from the very ‘jeopardy’ [to their health] alleged in appellees’ complaint”).

Moreover, Defendants’ reliance on *Spokeo* is misplaced; the case in fact shows why Plaintiffs have standing here. The plaintiff in *Spokeo*, Thomas Robins, alleged that the defendant, a search engine company, displayed information about him that was inaccurate. Some of the inaccuracies were trivial, such as showing an incorrect zip code. *See* 136 S. Ct. at 1550 (“It is difficult to imagine how the dissemination of an incorrect zip code, without more, could work any concrete harm.”). But others were more material, which Mr. Robins alleged made him “appear overqualified for jobs he might have gained” (such as that he had a graduate degree, which he did not), which thereby harmed his “employment prospects.” *Id.* at 1554 (Ginsburg, J.,

dissenting). The Supreme Court criticized the lower courts for “elid[ing]” the distinction between injuries that are “particularized” and “concrete,” *id.* at 1558 (majority opinion) – but it did not resolve whether any or all of Mr. Robins’s alleged harms were sufficient.

On remand, the Ninth Circuit held that Mr. Robins’s alleged harms were sufficient, precisely because his allegation was that Spokeo’s *methodology* was too flimsy, in violation of the Fair Credit Reporting Act’s requirement that credit reporting agencies (of which Spokeo was alleged to be one) “follow reasonable procedures to assure maximum possible accuracy” of the information they report. *Robins v. Spokeo, Inc.*, 867 F.3d 1108, 1114 (9th Cir. 2017) (“*Spokeo II*”) (citing 15 U.S.C. § 1681e(b)). Just as Congress required that credit reporting agencies “follow reasonable procedures to assure maximum possible accuracy” of consumers’ information, 15 U.S.C. § 1681e(b), Congress required that 340B ceiling prices be calculated under “precisely defined standards and methodology,” 42 U.S.C. §§ 256b(d)(1)(B)(i)(I). And just as the reason Congress required such “reasonable procedures” under the Fair Credit Reporting Act was to “curb the dissemination of false information by adopting procedures designed to decrease that risk,” *Spokeo*, 136 S. Ct. at 1550, the reason Congress mandated that HHS promulgate more precise standards was to “prevent overcharges.” 42 U.S.C. § 256b(d)(1)(A). Thus, particularly because Congress’s “judgment” in this regard is “instructive and important,” *Spokeo*, 136 S. Ct. at 1549, Defendants’ delay has harmed the interests Congress intended to protect by mandating the adoption of the more precise methodology reflected in the Final 340B Rule. Plaintiffs thus would have standing to challenge Defendants’ delay even in the absence of their informational injury, discussed above.

Third, the 2010 amendments also conferred procedural rights on 340B providers that have been and continue to be infringed by Defendants’ delay. Where Congress has “accorded a

procedural right to protect [a party's] concrete interests,” infringement of that procedural right itself constitutes an injury in fact, an injury the party “can assert . . . without meeting all the normal standards for redressability and immediacy.” *Massachusetts v. E.P.A.*, 549 U.S. 497, 517–18 (2007) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 573 n.7 (1992)). Such procedural harm is sufficient, and can be redressed, whenever “the procedural step was connected to the substantive result”; there is no requirement to show that vindication of the procedural right would have led to a “different substantive result.” *American Rivers v. Federal Energy Regulatory Comm’n*, 895 F.3d 32, 42 (D.C. Cir. July 6, 2018) (citations omitted).

Here, several aspects of the 2010 amendments created procedural rights. For example, they entitled 340B providers to have the prices they pay for 340B drugs calculated under “precisely defined standards and methodology.” 42 U.S.C. § 256b(d)(1)(B)(i)(I). Similarly, they conferred on 340B providers a procedural right to seek and obtain access to ceiling price data. And although Congress did not create a private right of action, its requirement that monetary penalties be imposed when drug companies overcharge 340B providers created yet another procedural right: a right to request that HHS impose penalties if a 340B provider learns that it has in fact been overcharged. Each of those procedural rights falls squarely within the rule reflected in cases such as *American Rivers*. See 895 F.3d at 42 (explaining that “[w]here . . . a party alleges deprivation of its procedural rights, courts relax the normal standards of redressability and imminence” and thus the plaintiffs “d[id] not need to show that the preparation of an Environmental Impact Statement would have led to a different ultimate result, but only that the requirement for such a report is connected to the ultimate decision”). See also *Watt v. Energy Action Educ. Found.*, 454 U.S. 151, 162 (1981) (holding that California had standing to challenge the Interior Department’s “refusal to experiment” with alternative bidding systems for

off-shore oil and gas leases because, even if California could not show that it would have been granted more leases under an alternative process, it was harmed by Interior's violation of its "statutory obligation to determine through experiment which bidding system works best"); *Zivotofsky ex rel. Ari Z. v. Sec'y of State*, 444 F.3d 614, 619 (D.C. Cir. 2006) ("[A] concrete and particular injury for standing purposes can also consist of the violation of an individual right conferred on a person by statute.").

For these reasons, Plaintiffs have suffered an Article III injury in fact.

B. Plaintiffs' Injuries Would Be Redressed By A Judgment In Their Favor.

Article III also requires that it be "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth*, 528 U.S. at 180-81. Defendants argue it is "speculat[ive]" to assert that "a favorable decision will remedy the harm caused by any manufacturer overcharging," because "it is possible" that "rather than to sell its drugs at prices mandated under the 340B Drug Pricing Rule," a manufacturer "may choose to leave the 340B Program." Defs.' Mem. at 12. Thus, Defendants argue, "[r]edressability would 'hinge on the response of the regulated (or regulable) third party [*i.e.*, the manufacturers] to the government action,' *i.e.*, on 'unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict.'" *Id.* at 11 (quoting *Lujan*, 504 U.S. at 562).

It is not Plaintiffs but Defendants who are engaging in "speculation." Even Defendants cannot dispute that some drug companies will remain in the program, and that most will comply with their obligations under the law, which in turn will protect 340B providers from overcharges. Indeed, the likelihood that *any* drug companies will leave the 340B program is remote, because doing so would render their drugs uncovered by any Medicaid program anywhere in the country.

See 42 U.S.C. §§ 1396r-8(a)(1) & 256b(a). In short, it requires no speculation to conclude that requiring public disclosure of ceiling prices calculated under a mandated methodology, particularly when combined with the threat of civil money penalties, will decrease the likelihood that drug companies will overcharge 340B providers.

The Supreme Court rejected arguments almost identical to Defendants' in *Akins* and *Massachusetts v. E.P.A.*, 549 at 497. In *Akins*, the Federal Election Commission had discretion to decide whether a "political organization" had to disclose its donors and members. Thus, it was "possible that even had the FEC agreed with [the plaintiffs'] view of the law," *i.e.*, if AIPAC was in fact a "political organization," the FEC "would still have decided in the exercise of its discretion not to require AIPAC to produce the information." 524 U.S. at 25. But that did not render the injury non-redressable, because "we cannot *know* that the FEC would have exercised its prosecutorial discretion in this way." *Id.* (emphasis added). In other words, because it was *possible* that AIPAC would have been required to disclose its donors if it were designated a "political organization" – even though it was not *certain* that it would be required to do so – the plaintiffs had standing to challenge the lack of such a designation.

Similarly, in *Massachusetts v. E.P.A.*, Massachusetts's injury was its receding coastline, an injury the Court held gave it standing to challenge EPA's failure to regulate greenhouse gases. 549 U.S. at 522-23. EPA conceded "the existence of a causal connection between manmade greenhouse gas emissions and global warming," but argued that "its decision not to regulate greenhouse gas emissions from new motor vehicles contributes so insignificantly to petitioners' injuries that the Agency cannot be haled into federal court to answer for them." *Id.* at 523. The Court rejected that argument as "rest[ing] on the erroneous assumption that a small incremental step, because it is incremental, can never be attacked in a federal judicial forum." *Id.* "That a first

step might be tentative does not by itself support the notion that federal courts lack jurisdiction to determine whether that step conforms to law.” *Id.* See also, e.g., *Friends of the Earth*, 528 U.S. at 185 (explaining that environmental plaintiffs had standing because “Congress has found that civil penalties in Clean Water Act cases do more than promote immediate compliance by limiting the defendants’ economic incentive to delay its attainment of permit limits; *they also deter future violations*”) (emphasis added); *In re Idaho Conservation League*, 811 F.3d 502, 510 (D.C. Cir. 2016) (holding that plaintiffs had standing to challenge EPA’s delay in implementing rules requiring that polluters “put aside funding . . . or otherwise demonstrate that funding is available” for potential future clean-up efforts, because promulgation of such rules “would strengthen hardrock mining operator’s *incentives* to minimize ongoing hazardous releases”) (emphasis added); *Air Line Pilots Ass’n, Int’l v. Chao*, 889 F.3d 785, 788-89 (D.C. Cir. 2018) (pilot union had standing to challenge the grant of a license to an Irish airline because entry of competitor pilots “harms the Unions’ members by exposing them to *potential* job loss, wage and hour cuts, and other competitive pressures”) (emphasis added).¹

¹ For these reasons, the two cases Defendants cite do not help them. In *Lujan* (cited in Defs.’ Mem. at 11), the plaintiffs’ asserted injuries were to their research and aesthetic interests in species that might go extinct (injuries that were themselves highly speculative). The reason their redressability theory failed was because they merely sought a declaratory judgment that the Endangered Species Act had extraterritorial reach; nothing they sought would require that anyone take any action to actually protect endangered species abroad. 504 U.S. at 569-71. In *National Wrestling Coaches Association v. Department of Education*, 366 F.3d 930 (D.C. Cir. 2004), the plaintiffs challenged Title IX regulations that they alleged resulted in some colleges discontinuing their varsity wrestling programs. But they offered “nothing but speculation to substantiate their assertion that a favorable judicial decision would result in schools altering their independent choices regarding the restoration or preservation of men’s wrestling programs,” *id.* at 933, especially because those schools would still be required to comply with other regulations that required that athletic opportunities be provided in a manner that equally accommodated both genders. *Id.* at 940. Here, in contrast to those cases, upon promulgation of the Final 340B Rule drug companies will immediately be required to comply with it.

In sum, just as Defendants' delay has caused Plaintiffs injuries in fact, requiring Defendants to implement the Final 340B Rule would redress those injuries.

II. THE ASSOCIATION PLAINTIFFS ALSO HAVE STANDING.

“An association has standing to bring suit on behalf of its members when [1] its members would otherwise have standing to sue in their own right, [2] the interests at stake are germane to the organization's purpose, and [3] neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.” *Friends of the Earth, Inc. v. Laidlaw Enviro. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000); *see also Ctr. for Sustainable Econ. v. Jewell*, 779 F.3d 588, 597 (D.C. Cir. 2015) (noting that the germaneness requirement is aimed at determining whether the association's “specific goal in th[e] litigation,” and its “specific expertise,” are “pertinent to [its] core organizational mission”).

Here, four associations – the American Hospital Association (AHA), America's Essential Hospitals, the Association of American Medical Colleges and 340B Health – have sued on behalf of their members that are 340B providers. *See* Ex. 1 at ¶ 4; Ex. 2 at ¶ 4; Ex. 3 at ¶ 4; Ex. 4 at ¶ 4. As discussed above, those members would otherwise have standing to sue in their own right. *See* § I, *supra*. Defendants have not otherwise challenged the Association Plaintiffs' standing to bring this action. In any event, the interests of the members that they seek to protect through this action are germane to their respective organizational purposes. Ex. 1 at ¶ 6; Ex. 2 at ¶ 6; Ex. 3 at ¶ 6; Ex. 4 at ¶ 6. And although neither the claim asserted nor the relief requested requires the participation of individual members in this lawsuit, individual members of two of the associations have in fact joined as plaintiffs. *See* Ex. 5 at ¶ 2 (Genesis is a member of 340B Health and the AHA); Ex. 6 at ¶ 2 (Kearny County Hospital is member of the AHA); Ex. 7 at ¶ 2 (Rutland Regional is a member of 340B Health and the AHA).

III. THE COURT SHOULD ENTER AN ORDER DIRECTING DEFENDANTS TO MAKE THE 340B RULE EFFECTIVE BY JANUARY 1, 2019 AND TO POST CEILING PRICES BY APRIL 1, 2019.

Defendants have challenged Plaintiffs' motion for summary judgment on the grounds that Plaintiffs lack standing. They have not contested Plaintiffs' claims that their delayed implementation of the 340B Final Rule is arbitrary and capricious, an abuse of discretion, and contrary to law, and agency action unreasonably delayed, in violation of the Administrative Procedure Act. Defendants therefore concede the key issues on the merits of Plaintiffs' claims. Thus, if the Court denies Defendants' motion to dismiss, it should grant summary judgment to Plaintiffs and order Defendants to implement the 340B Final Rule by January 1, 2019, as they have proposed to do. *See* 83 Fed. Reg. 55,135 (Nov. 2, 2018); Defs.' Mot. to Stay, ECF No. 15, at 4. Plaintiffs are submitting a new proposed order that reflects that commitment, and that also directs Defendants to post 340B ceiling prices no later than April 1, 2019.

As to Defendants' obligation to post 340B prices, both the 2010 amendments and the 340B Final Rule require that HHS post the ceiling prices on a secure website available to 340B providers. 42 U.S.C. § 256b(d)(1)(B)(iii); 82 Fed. Reg. 1,210, 1,229 (January 5, 2017). As Plaintiffs have previously pointed out, they recently learned that Defendants will not commit to any date by which they will comply with this provision, even if the final regulations are made effective on January 1, 2019. *See* Pls.' Opp. To Defs.' Mot. to Stay, ECF No. 16 ("Pls.' Stay Opp."), at 7. As Plaintiffs have explained, there is no basis for further delaying the posting: Defendants should begin posting ceiling prices on the HHS website as soon after January 1, 2019 as possible, and in any event no later than April 1, 2019. *See* Pls.' Stay Opp. at 7; Pls.' S.J. Mem. at 26.

The requirement to post has been in effect for more than eight years. In addition, the Healthcare Resources and Services Administration (HRSA) has had the funding for the IT system to post ceiling prices since 2014, and testified in July 2017 – sixteen months ago – that the system would be ready in “the coming months.” *See* Pls.’ S.J. Mem. at 23-24 (citing *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., Transcript, at 47, 2017 WL 3104702 (Jul. 18, 2017)). Defendants’ response to this argument was that it cannot post the ceiling prices on the website by January 1, 2019. Defs.’ Reply in Supp. of Mot. to Stay, ECF No. 17, at 3. Plaintiffs understand that HRSA needs information from both the Center for Medicare & Medicaid Services and drug companies before it can post ceiling prices. This is why Plaintiffs have asked for an order directing Defendants to comply with this requirement no later than April 1, 2019, which is warranted; Defendants have had more than eight years to plan this website and were given the funds to get it up and running four years ago.

CONCLUSION

Each of the Plaintiffs, hospitals and associations alike, have been and continue to be harmed in multiple ways by Defendants’ delay, and thus have standing to challenge it. The delay is not only indefensible – it is un-defended: Defendants offer no response to the merits of Plaintiffs’ motion for summary judgment. The Court should enter judgment in Plaintiffs’ favor, as reflected in the attached, updated proposed order.

Dated: November 21, 2018

Respectfully submitted,

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