UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, *Plaintiffs,* –v– THE DEPARTMENT HEALTH AND HUMAN SERVICES, *et al.*, *Defendants.*	**Case No. 1:18-cv-2112**

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Dated: September 11, 2018

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INTRODUCTION

Four hospital associations (the American Hospital Association, America's Essential Hospitals, the Association of American Medical Colleges and 340B Health) (the "Association Plaintiffs"), and three hospital systems (Genesis HealthCare System, Kearny County Hospital and Rutland Regional Medical Center) (the "Hospital Plaintiffs") seek a declaration that the most recent and fifth delay by the defendants, the Department of Health and Human Services (HHS) and the Secretary of HHS, of the effective date of an important regulation that HHS issued in final form on January 5, 2017 (the "Final 340B Rule") is unlawful, and an order that the Secretary make the Final 340B Rule effective within 30 days after judgment. Statutory amendments passed in 2010 require HHS to issue the regulation in order to ensure that drug companies give hospitals, community health centers, and other federally funded clinics that disproportionately serve the poor the discounted price on prescription drugs that has been required since 1992 by section 340B of the Public Health Service Act, 42 U.S.C. § 256b. Congress adopted the 2010 law in response to the HHS Office of Inspector General's (OIG's) reports documenting numerous instances when drug companies have illegally overcharged hospitals, community health centers, and other federally funded clinics for prescription drugs, and to implement the OIG's recommendations that HHS be given the authority to facilitate compliance with section 340B and to penalize violations.

Defendants' repeated delays in implementing the Final 340B Rule are causing significant harm to the Hospital Plaintiffs, and, by extension, their vulnerable communities whom Congress intended to benefit from the 340B Program.

STATEMENT OF FACTS

A. The 340B Program

Congress created the 340B Program in 1992 to provide certain hospitals, community health centers and other federally funded clinics serving low-income patients ("340B providers")[1] with outpatient drug discounts comparable to those Congress had made available to state Medicaid agencies in 1990. In fact, after Congress passed the Medicaid drug rebate program, it became concerned that federally funded clinics and public hospitals were experiencing substantial increases in their outpatient drug costs. H.R. REP. No. 102–384(II), at 11 (September 22, 1992). Under the 340B Program, private prescription drug companies, as a condition of having their outpatient drugs covered through Medicaid, are required to enter into a 340B Pharmaceutical Pricing Agreement with the Secretary of HHS pursuant to which they must offer 340B providers outpatient drugs at or below an applicable, discounted, statutorily-determined price, referred to as the "ceiling price." 42 U.S.C. § 256b(a)(1).

The ceiling price, the maximum per-unit price that can be charged to 340B providers for outpatient drugs, is key to the discounts made available under the 340B Program. Under the statute, 42 U.S.C. § 256b(a), the ceiling price is calculated by subtracting the unit rebate amount from the "average manufacturer price" (AMP). The amount of the rebate is generally the greater of (a) the "minimum [statutory] rebate percentage," currently either 23.1, 17.1 or 13 percent depending on the type of drug, or (b) the difference between AMP and "the lowest price" the drug company has charged during the "rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity," whichever is greater. 42 U.S.C. § 1396r-8(c)(1).

[1] The statute refers to 340B providers as "covered entit[ies]." 42 U.S.C. § 256b(a)(4).

The statute also provides for a larger rebate when a drug company has increased its drug prices faster than the rate of inflation. *Id.* § 1396r-8(c)(2)(A). Historically, this inflation-based rebate could have resulted in negative 340B prices. Effective January 1, 2010, however, Congress eliminated the anomaly of negative pricing by requiring the Medicaid program, on which the 340B rebates are based, to limit the rebate amount to 100% of the AMP. 42 U.S.C. § 1396r-8(c)(2)(D).

Congress enacted the 340B Program "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. REP. NO. 102-384(II), at 12 (September 22, 1992). A 2011 report from the U.S. Government Accountability Office ("GAO") found that this is exactly what happened and that 340B providers have used the additional resources to provide critical healthcare services to communities with underserved populations that could not otherwise afford these services—for instance, by increasing service locations, developing patient education programs, and providing translation and transportation services. U.S. Gov't Accountability Off., GAO-11-836, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 17-18 (2011) ("2011 GAO Report"), http://www.gao.gov/assets/330/323702.pdf. 340B program savings totaled $6 billion in 2015. Final Rule, 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210, 1,227 (January 5, 2017). The Health Resources Services Administration (HRSA) is the division of HHS that administers the 340B program.

B. OIG and Congressional Recognition of Problems with the 340B Program

Despite the 340B Program's recognized value, HRSA has faced significant challenges in ensuring that drug companies are providing the mandated discount. Before 2010, the OIG issued multiple reports that identified weaknesses in the oversight of drug company compliance with

the requirements of the 340B Program. In a March 2003 report, the OIG reviewed the sales of 11 prescription drugs sold by five drug companies over a one-year period and determined that all five companies had overcharged 340B providers for the 11 drugs, by an estimated $6.1 million. Department of Health and Human Services Office of the Inspector General, *Pharmaceutical Manufacturers Overcharged 340-B Covered Entities*, A-06-01-00060, at 3 (March 10, 2003). https://oig.hhs.gov/oas/reports/region6/60100060.pdf.

In an October 2005 report, the OIG found systemic problems with the accuracy and reliability of HRSA's record of 340B ceiling prices. Department of Health and Human Services, Office of the Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072, at 10-11 (October 2005), https://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf. The OIG also found that HRSA had no procedure to convert ceiling prices with negative values into practical ceiling prices. *Id.* at 14.[2] It further found that HRSA lacked the oversight mechanisms and authority to ensure that 340B providers pay no more than the 340B ceiling price and that participating providers could not independently verify that they receive the correct discount. *Id.* at 15-18.

The OIG also noted that, unlike under the Medicaid Program, HHS had no authority to impose civil money penalties for noncompliance with the requirements of the 340B Program. The OIG concluded that HRSA's only statutory authority to enforce the 340B Program requirements – terminating the Pharmaceutical Pricing Agreement – was too extreme to be used because it meant the drug company would be excluded both from 340B and Medicaid, which

[2] At the time of the OIG Report, because the statute provides for a larger rebate when a drug company has increased its drug prices faster than the rate of inflation, the rebate could have exceeded the AMP and resulted in a negative 340B price. As discussed above, in 2010, the law was changed to limit the rebate amount to 100% of the AMP, making the lowest price zero. 42 U.S.C. § 1396r-8(c)(2)(D).

would adversely affect access to medications for the millions of Medicaid beneficiaries and patients of 340B providers. *Id.* at 18. The OIG recommended that HRSA establish standards for calculating 340B ceiling prices, including a conversion factor for negative ceiling prices, and that HRSA institute oversight mechanisms to validate the prices charged to covered entities. *Id.* at 21-22. At the time of this report, HRSA reported to the OIG that it recommended to drug companies that they charge a penny for drugs when the calculated 340B ceiling price was zero or less. *Id.* at 14. This was known as the "penny pricing policy." In 2011, HRSA put the policy in writing.[3]

In a July 2006 report, the OIG found that in one month, 14 percent of total purchases made by the 70 sampled 340B providers exceeded the 340B ceiling prices, resulting in total overpayments of $3.9 million. Department of Health and Human Services, Office of the Inspector General, *Review of 340B Prices*, OEI-05-02-0073 at 11 (July 2006), https://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf. The largest overpayments in the sample resulted from the drug companies' inappropriate handling of negative ceiling prices that resulted from application of the statutory inflation penalty in a manner that was inconsistent with HRSA's penny pricing policy. *Id*. at 14. As a result, the sampled 340B providers paid up to 450,000 percent over the 340B ceiling price. *Id.* Following these OIG reports, the OIG Deputy Inspector General for Evaluation and Inspections testified before Congress that "HRSA should seek legislative authority to impose civil monetary penalties for situations of noncompliance . . . because the current penalty of kicking manufacturers out of Medicaid and the 340B program is so draconian that it's not likely to be utilized." *Oversight and Administration of the 340B Discount Drug*

[3] HRSA, *Clarification of Penny Pricing Policy*, Release No. 2011-2 (November 21, 2011) at https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/pennypricingclarification112111.pdf. HHS has always taken the position that the ceiling price cannot be a negative number or zero because the statute contemplates a payment to the drug company. 82 Fed. Reg. at 1,210, 1,214 (January 5, 2017).

Program: Improving Efficiency and Transparency—Hearing Before the H. Subcommittee on Oversight and Investigations of the Comm. On Energy and Commerce, 109th Cong. (Dec. 15, 2005) (*December 2005 340B E&C Oversight Hearing*), https://www.gpo.gov/fdsys/pkg/CHRG-109hhrg30139/html/CHRG-109hhrg30139.htm, pp. 8-9, 19. He also testified that HRSA should seek authority to disclose ceiling prices because its inability to release ceiling price information undermines HRSA's ability to ensure that 340B providers are getting the appropriate ceiling price. *Id.* at 8-9.

C. Congressional Response to the OIG Recommendations

This drumbeat of problems identified by the OIG led Congress in 2010 to enact several important revisions to the 340B statute as part of the Affordable Care Act ("ACA"). Pub. L. 111-148, 124 Stat. 119 (March 23, 2010), as amended by Pub. L. 111-152, 124 Stat. 1029, 1082 (March 30, 2010). In addition to expanding the types of hospitals that could qualify as 340B providers, Congress required the Secretary to adopt a number of measures to improve compliance, including measures to improve the accuracy and transparency of ceiling prices, and penalties on drug companies for noncompliance.

To improve the accuracy of ceiling prices, Congress required the Secretary to "develop[] . . . a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers." 42 U.S.C. § 256b(d)(1)(B)(i). In developing that "system," the Secretary must, among other things, "[d]evelop[] and publish[] through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices" and "[c]ompar[e] regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary." *Id.* § 256b(d)(1)(B)(i)(I) and (II).

Following the Inspector General's recommendation, Congress also required the Secretary to give 340B providers access, through an HHS website, to "the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary." *Id.* § 256b(d)(1)(B)(iii). Finally, in order to "improve . . . compliance by manufacturers," 42 U.S.C. § 256b(d)(1)(A), Congress concluded that there needed to be financial penalties for violations to "prevent overcharges and other violations of the discounted pricing requirements." *Id.* Thus, the statute required the Secretary to impose "sanctions in the form of civil monetary penalties" against drug companies that have "knowingly and intentionally" "overcharge[ed] a covered entity," up to $5,000 "for each instance of overcharging." *Id.* § 256b(d)(1)(B)(vi). The amended statute required the Secretary to adopt "standards" for imposing civil monetary penalties, which were required "to be promulgated by the Secretary not later than 180 days after March 23, 2010." *Id.*

D. HHS Implementation of 340B Provisions

HHS did not meet that statutory deadline. Instead, on September 20, 2010, HHS issued an Advance Notice of Proposed Rulemaking seeking stakeholder input on its new civil money penalties authority and on the other provisions it was required to implement, including the establishment of procedures to verify and publish ceiling prices. *340B Drug Pricing Program Manufacturer Civil Money Penalties*, 75 Fed. Reg. 57,230 (September 20, 2010).

HHS then spent almost five years considering that input and finally, on June 17, 2015, issued proposed regulations. *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Money Penalties Regulation*, 80 Fed. Reg. 34,583 (June 17, 2015). The proposed regulation addressed concerns about the accuracy of ceiling prices by, among other things: (1) requiring drug companies to calculate 340B ceiling prices on a quarterly basis, to six decimal places, and "for the smallest unit of measure"; (2) providing a methodology for calculating the ceiling price when the statutory penalty for increasing drug prices faster than inflation results in a price of $0

(*i.e.*, promulgating the penny pricing policy, described above); and (3) providing a detailed mechanism for calculating ceiling prices for new drugs.[4] *Id.* at 34,588. It also implemented Congress's directive to give 340B providers access to ceiling prices, by providing that HRSA "will publish" those ceiling prices, rounded to two decimal places. *Id.* Finally, the proposed regulation set forth detailed standards for the assessment and imposition of civil monetary penalties, including defining what constitutes an "instance of overcharging." *Id.*

In April 2016, HHS reopened the comment period to invite additional comments on several specific areas, including the penny pricing policy, the methodology that drug companies utilize when estimating the ceiling price for a new 340B drug, and the definition of "knowingly and intentionally" for the imposition of civil money penalties on drug companies. 81 Fed. Reg. 22,960 (April 16, 2016).

HHS received approximately 105 comments on the proposed regulations. *See* 82 Fed. Reg. 1,210, 1,211 (January 5, 2017). The comments addressed almost every aspect of the proposed regulations, including HHS's authority to adopt the regulations, the timing of implementation, the terminology definitions, the quarterly ceiling price reporting requirement, and decimal place rounding. *Id.* at 1211-28. There were especially extensive comments submitted on the policy for pricing based on the statutory inflation penalty, *id.* at 1214-17, the new drug ceiling price methodology, *id.* at 1217-20, and the civil monetary penalty standards, *id.* at 1220-27. On January 5, 2017, the Department issued the Final 340B Rule, *id.* at 1229-30, which largely implemented the regulation HHS had proposed almost nineteen months earlier.

[4] Because the ceiling price is based on pricing data from the previous quarter and for new drugs there are no sales data from the previous quarter, HHS developed a methodology to calculate ceiling price calculations for new drugs. 80 Fed. Reg. at 34,585.

The Final 340B Rule set an effective date of March 6, 2017. *Id.* at 1,210. The Department stated, however, that because that date would "fall[] in the middle of a quarter," it would wait to "begin enforcing the requirements of this final rule" until "the start of the next quarter, which begins April 1, 2017." *Id.* at 1211. The Department expressly found that "this timeframe provides manufacturers sufficient time to adjust systems and update their policies and procedures." *Id.*

E. The Current Administration's Change in Course

The current administration took office on January 20, 2017. Defendants have not outwardly revoked the Final 340B Rule but instead have postponed the effective date of the Final 340B Rule five separate times. Those delays continue until at least July 2019, unless overturned by the Court, and have the same effect as revoking the rule.

First Delay (15 days). On January 24, 2017, the administration froze all pending regulations. 82 Fed. Reg. 8,346 (January 24, 2017). That freeze extended the effective date of the Final 340B Rule to March 21, 2017. 82 Fed. Reg. 12,508 (March 6, 2017).

Second Delay (2 months). On March 20, 2017, HHS promulgated an interim final rule further delaying the effective date, this time to May 22, 2017. 82 Fed. Reg. 14,332 (March 20, 2017). The proffered rationales for the delay were "to consider questions of fact, law, and policy raised in the rule, consistent with the 'Regulatory Freeze Pending Review' memorandum," "to provide affected parties sufficient time to make needed changes to facilitate compliance," to address "substantive questions raised" by the Final 340B Rule, and because "we intend to engage in longer rulemaking." *Id.* at 14,333.

Third Delay (4 months). Two months after the Second Delay, on May 19, 2017, HHS issued a final rule, delaying implementation yet again, this time to October 1, 2017. 82 Fed. Reg.

22,893 (May 19, 2017). The Department offered a single rationale: that delay was necessary "to provide adequate time for compliance and to mitigate implementation concerns." *Id.* at 22,894.

Fourth Delay (9 months). When HHS proposed an additional nine-month delay, it received nearly one hundred comments, with an overwhelming majority opposing further delay. *See* 82 Fed. Reg. 45,511, 45,512 (September 29, 2017). The Department nonetheless delayed the effective date to July 1, 2018. HHS rehashed some of the prior rationales, but also claimed that delay was necessary "to align with the Administration priorities of analyzing final, but not yet effective, regulations, and removing or minimizing unwarranted economic and regulatory burdens related to the Affordable Care Act," and thereby to "comply[] with Executive Order 13765 to delay implementation of provisions of [the ACA]" on various grounds. *Id.* at 45,512-13.

Fifth Delay (12 months). On May 7, 2018, HHS issued a notice of proposed rulemaking to delay the effective date another twelve months, offering old and new justifications. 83 Fed. Reg. 20,009 (May 7, 2018). The Department claimed that delay of the civil monetary penalties provision "should have no adverse effect given that other more significant remedies are available to entities that believe that they have not been provided the full discount." *Id.* at 20,009. Dozens of individuals and organizations submitted feedback, many pointing out the fallacy of HHS's position on civil monetary penalties, and noting that 340B providers "cannot audit manufacturers or sue [them] in court," and without implementation of the Final 340B rule cannot even "check if they are being charged the right price." 83 Fed. Reg. 25,943, 25,945 (June 5, 2018).

On June 5, HHS issued the final rule being challenged in this case, delaying the effective date to July 1, 2019. *Id.* The Department reiterated some of the prior rationales but also added this: "[T]he 340B Program is a complex program that is affected by changes in other areas of

health care. HHS has determined that this complexity and the changing environment warrants further review of the final rule, and that delaying the final rule affords HHS the opportunity to consider alternative and supplemental regulatory provisions and to allow for sufficient time for any additional rulemaking." *Id.* at 25,945. HHS stated its belief that the "delay will [not] adversely affect any of the stakeholders in a meaningful way." *Id.* at 25,944.

F. Procedural History

Plaintiffs in this action are the American Hospital Association, America's Essential Hospitals, the Association of American Medical Colleges, 340B Health, Genesis HealthCare System, Kearny County Hospital and Rutland Regional Medical Center. The Hospital Plaintiffs rely heavily on the price differential created by Congress in the 340B Program to generate resources that are used to provide critical health care programs for the vulnerable populations each serves. Complaint ¶ 18. Defendants' repeated delays in implementing the Final 340B Rule are causing significant harm to the Hospital Plaintiffs, and, by extension, their vulnerable patients whom Congress intended to benefit from the 340B Program. *Id.* ¶¶ 9, 18. Defendants' actions are also causing harm to other 340B providers, of which there are approximately 2,487 nationwide, all or virtually all of which are members of the Association Plaintiffs. *Id.* ¶ 9.

Plaintiffs challenge the Defendants' most recent delay of the Final 340B Rule on the grounds that the delay is arbitrary and capricious, an abuse of discretion, and is contrary to law, in violation of section 706(2)(A) of APA. Plaintiffs also challenge the Defendants' action on the grounds that the Defendants have unreasonably delayed implementing the Final 340B Rule in violation of section 706(1) of the APA.

ARGUMENT

The 340B Program provides crucial relief from high drug prices to hospitals, community health centers, and other federally funded clinics that rely on the 340B savings to fund critical programs for their low-income, uninsured, and underinsured patient populations. In 2010, Congress endorsed the value of the program by expanding the types of hospitals that could qualify, to include certain children's hospitals, free-standing cancer hospitals, critical access hospitals, and sole community hospitals.[5] Congress also recognized serious problems, including drug companies' compliance, and it directed HHS to adopt a number of measures to enhance compliance. Among those were the three measures at issue in this litigation, all of which were intended to implement recommendations of the OIG. Specifically, the legislation required the Secretary to adopt measures that would improve the accuracy and transparency of ceiling prices, and within 180 days to adopt regulations providing for imposition of civil money penalties on drug companies that violated the law. ACA § 7102, 124 Stat. at 825. The Final 340B Rule does this by: (1) setting forth a methodology for calculating ceiling prices (including for new drugs and drugs subject to the statutory inflation penalty); (2) requiring the publication of ceiling prices; and (3) setting forth detailed standards for the assessment and imposition of civil monetary penalties. 82 Fed. Reg. 1,210.

Almost seven years after the ACA was enacted, after soliciting comment three times, once to an advanced notice of proposed rulemaking and twice to a proposed rule, on January 5, 2017, HHS issued the Final 340B Rule, with a 60-day effective date. *Id*. The Department expressly found that "this timeframe provides manufacturers sufficient time to adjust systems and update

[5] ACA § 7101, 124 Stat. at 821. Since 1992, 340B providers have included federally funded health centers and clinics providing services such as family planning, AIDS intervention, and hemophilia treatment, as well as public and certain not-for-profit hospitals serving a large proportion of low-income or uninsured populations. 42 U.S.C. §§ 256b(a)(4)(A)-(L).

their policies and procedures." *Id.* at 1,210-11. As explained below, the latest delay in issuing the final rule violates two provisions of the Administrative Procedure Act. [6]

I. HHS's Fifth Delay of the Effective Date of the Final Rule Implementing the 340B Compliance Measures, for an Additional Year, Was Arbitrary and Capricious.

The Administrative Procedure Act requires courts to "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2). In *Motor Vehicle Mfrs. Ass'n of U.S.* v. *State Farm Mut. Auto Ins. Co.*, 463 U.S. 29 (1983), the Supreme Court applied this provision to invalidate a decision of the National Highway Traffic Safety Administrator to rescind regulations that required airbags or automatic seat belts in new cars. In that case, as in this one, a new Administration reversed the course that had been adopted by its predecessor. The Court held that "an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance." *Id.* at 42. In this case, the five actions delaying the rule's effective date by two and a half years are a change in course with an effect no different than repealing a rule. *Clean Air Council* v. *Pruitt*, 862 F.3d 1, 7 (D.C. Cir. 2017) (an order delaying the rule's effective date is tantamount to amending or revoking a rule). This action not only fails to meet the regular

[6] Federal Rule of Civil Procedure 56 requires a court to grant summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In APA cases, however, the summary judgment standard "functions slightly differently, because the reviewing court generally reviews the agency's decision as an appellate court addressing issues of law." *Policy & Research, LLC* v. *United States Dep't of Health & Human Servs.*, 313 F. Supp. 3d 62, 74 (D.D.C. 2018) (citation and alterations omitted). In other words, "the entire case on review is a question of law, and only a question of law." *Marshall Cty. Health Care Auth.* v. *Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993). In the context of APA cases, summary judgment "serves as the mechanism for deciding, as a matter of law, whether agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Alliance for Nat. Health U.S.* v. *Sebelius*, 775 F. Supp. 2d 114, 118 (D.D.C. 2011).

rulemaking standard, it does not come close to meeting the elevated standard it must meet for changing course.

Agency action is arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43. An agency is required to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Id.* (quoting *Burlington Truck Lines, Inc.* v. *United States*, 371 U.S. 156, 168 (1962) (internal quotations omitted). Courts "do not defer to the agency's conclusory or unsupported suppositions." *United Techs. Corp.* v. *Dep't of Def.*, 601 F.3d 557, 562 (D.C. Cir. 2010) (quoting *McDonnell Douglas Corp.* v. *Dep't of the Air Force*, 375 F.3d 1182, 1187 (D.C. Cir. 2004)). HHS's change in course by delaying the Final 340B Rule fails this test for two simple reasons: (1) HHS did not provide a coherent explanation for its decision to delay the Final 340B rule; and (2) HHS's claim that 340B Providers will not be affected had no support in the administrative record.

A. HHS Has Failed to Articulate a Plausible Rationale for Its Action.

In its most recent proposed and final rule implementing its most recent delay, HHS proffered the following reasons for the delay: (1) it intends to engage in additional or alternative rulemaking on these issues both generally and in light of the "Regulatory Freeze Pending Review" memorandum; (2) it is developing new comprehensive policies to address the rising costs of prescription drugs; (3) the delay will save the healthcare sector compliance costs as described in the January 2017 issuance of the final rule; and (4) the delay will provide regulated entities with needed time to implement the requirements of the rule. 83 Fed. Reg. at 25,944-45; 83 Fed Reg. at 20,009-10.

1. HHS's Principal Proffered Rationale – Consideration of Unspecified Policy Changes – Is Not a Plausible Basis for Delay.

In its proposed and final rule implementing its most recent delay, HHS stated that it intended to engage in additional or alternative new rulemaking on drug pricing issues in government programs, including Medicare Parts B (payment of physician services) and D (payment for prescription drugs), Medicaid, and the 340B program, that the delay was needed to allow time to consider more fully the substantial questions of fact, law, and policy identified during its review pursuant to the "Regulatory Freeze Pending Review" memorandum, and that the Department believes it would be counter-productive to effectuate the final rule before issuing additional or alternative rulemaking on these issues. 83 Fed. Reg. at 25,944; 83 Fed. Reg. at 20,009.

The statement that HHS plans to engage in some future rulemaking at some uncertain time that may or may not address directly or indirectly the issues that are the subject of the 340B Final Rule does not justify HHS's decision to repeatedly delay implementing the rule it has already issued through notice and comment rulemaking and that was designed to comply with directions in a statute and to address real problems that had been identified by Congress, the OIG and HHS. This is especially true because the agency has no other rulemaking in progress; it is unclear when, if ever, such rulemaking will occur; and there is no reason to believe such as-yet-begun rulemaking would address any of the issues that are the subject of the Final 340B Rule.

It took HHS almost seven years to issue the Final 340B Rule. If a federal agency could determine that the possibility of new or changed rules justifies not implementing a current rule, then it could legally justify any decision not to implement any rule. The possibility of new or changed rules cannot serve as a legitimate rationale for delay. *Pruitt*, 862 F.3d at 14 (EPA's two-year stay of implementation of portions of a final rule concerning certain greenhouse gas

emission while it reconsidered the rule was "arbitrary and capricious and in excess of statutory authority"). Instead, the agency must supply a "reasoned analysis [to support the] change." *State Farm*, 463 U.S. at 42. Here, HHS has not identified the change it may be seeking, so the analysis cannot even be done. In the meantime, absent a good reason not to do so, HHS must allow the rule it has implemented to become effective.

That is especially true where HHS has a statutory obligation to adopt the measures that are in the regulations. Here, Congress required the Secretary to impose "sanctions in the form of civil monetary penalties" against drug companies that have "knowingly and intentionally" "overcharge[ed] a covered entity," up to $5,000 "for each instance of overcharging." *Id.* § 256b(d)(1)(B)(vi). The statute required the Secretary to adopt "standards" for the imposition of civil monetary penalties, which were required "to be promulgated by the Secretary *not later than 180 days after March 23, 2010*." *Id.* (emphasis supplied). Congress also directed HHS to "[d]evelop[] and publish[] through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices" and "[c]ompar[e] regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary." 42 U.S.C. § 256b(d)(1)(B)(i)(I) and (II). Finally, Congress required the Secretary to give 340B providers access, through an HHS website, to "the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary." *Id.* § 256b(d)(1)(B)(iii).[7]

HHS apparently takes the position that Congress's directions can be ignored *indefinitely*. HHS does not even identify what policies are under consideration, why those policies would be

[7] The Secretary must also "[p]erform spot checks of sales transactions by covered entities," "[i]nquir[e] into the cause of any pricing discrepancies that may be identified," and "either tak[e], or require[e] manufacturers to take, such corrective action as is appropriate in response to such price discrepancies." *Id.* § 256b(d)(1)(B)(i)(III) and (IV).

inconsistent with the Final 340B Rule, or when they might be issued. In fact, it is difficult to imagine how any such unidentified policies would require change to the final regulation or, perhaps more importantly, how the 340B program can function as effectively as Congress intended without such regulations in place.

Moreover, irrespective of what "policy" changes the Department might consider in the future, no policy could rationally justify *not* implementing a statute that Congress expressly instructed the Department to implement. HHS does not have the authority to substitute its policy choices for those clearly made by Congress. For example, as required by the 2010 amendments to the 340B statute, the Final 340B Rule creates a process for imposing civil money penalties when a drug company is found to have overcharged a covered entity. HHS never explains how any policy changes under consideration, no matter what they may be, could justify not implementing a statutory requirement that a drug company that has been found to have overcharged, and thus to have been in violation of the law, must pay a penalty.

The statutorily required posting of ceiling prices on a website is a straightforward transparency provision: even if the Administration decided to make a change to how ceiling price is calculated, the prices would still need to be posted and any change in policy would require only that a different price be posted. In other words, setting aside the methodology by which ceiling prices are calculated, HHS has not identified any reason why ceiling prices should not be posted publicly.

That leaves the requirement for regulations standardizing the calculation of ceiling prices, particularly for new drugs and drugs with a calculated ceiling price of zero. Even if the Department were to adjust the calculation methodology, it will be many years before it does so;

it has not even stated that it has developed a new policy or issued a proposed rule. In the meantime, the drug companies are required to make the calculations and provide the discounts.

Moreover, delaying implementation of the final rule leaves HRSA without a legally enforceable mechanism for implementing the statute. Since Congress added these provisions in 2010 to ensure that HRSA would have the tools needed to provide appropriate oversight, the recent one-year delay of their implementation, after four previous delays adding up to 18 months, is plainly arbitrary and capricious.

2. HHS's Other Proffered Explanations Provide No Plausible Basis for Delay.

HHS offered three additional rationales for delaying the effective date of the 340B Final Rule. Each collapses after even a cursory analysis.

First, HHS stated that delay is justified because "HHS is developing new, comprehensive policies to address the rising costs of prescription drugs." 83 Fed. Reg. at 25,944. This is similar to the rationale discussed in section I.A.1, *supra*, since the Department did not identify the new policies or explain how they might relate to the 340B program. Moreover, HHS fails to even attempt to explain why the Final 340B Rule would interfere with other policies being considered to address rising drug costs. In fact, the Final 340B Rule furthers the goal of decreasing drug prices. It creates an effective penalty for over-charging (thus discouraging that behavior) and it reinforces the statutory penalty for increasing drug prices more quickly than the rate of inflation. This is entirely consistent with the goal of addressing the issue of the rising costs of prescription drugs.

Second, HHS claims that its most recent delay will save the healthcare sector compliance costs as described in the January 2017 issuance of the final rule. 83 Fed. Reg. at 25,945. But this rationale is inconsistent with its own Economic Analysis, included in the 340B Final Rule.

There, HHS took the position that the administrative burden of the rule was minimal because most aspects of the Final 340B Rule merely codify what drug companies are already required to do. 82 Fed. Reg. at 1227-28. And as to imposition of civil money penalties, HHS added that it did not anticipate a "significant economic impact." *Id*. HHS makes no attempt to reconcile these contradictory conclusions between HHS's Final 340B Rule and the Agency's recent final rule further delaying the effective date.

Third, HHS claims that it continues to believe that the delay will provide regulated entities with needed time to implement the requirements of the rule. 83 Fed. Reg. at 25,944. But HHS has already given regulated entities almost 18 months to comply with the Final 340B Rule even though it found, when it issued the rule, which gave drug companies 90 days to come into compliance, that "this timeframe provides manufacturers sufficient time to adjust systems and update their policies and procedures." 82 Fed. Reg. 1,210.

In sum, HHS's decision is arbitrary and capricious because it has "offered an explanation for its decision that runs counter to the evidence before the agency," and because the explanation "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43. *See also Fox* v. *Clinton*, 684 F.3d 67, 80 (D.C. Cir. 2012) (the Department's judgment was arbitrary and capricious for want of reasoned decision-making); *Tripoli Rocketry Ass'n* v. *Bureau of Alcohol, Tobacco, Firearms, and Explosives*, 437 F.3d 75, 77 (D.C. Cir. 2010) (the agency's decision cannot be sustained because it never provided a coherent explanation); *Allentown Mack Sales & Serv., Inc.* v. *NLRB*, 522 U.S. 359, 374 (1998) ("Courts . . . set aside agency regulations . . . [that] are not supported by the reasons the agencies adduce.") (Rehnquist, C.J., concurring).

B. HHS's Claim that 340B Providers Will Not Be Affected by Its Failure to Implement the Final 340B Rule Has No Support in the Rulemaking Record.

As demonstrated above, none of the rationales proffered by HHS provide a plausible basis for its most recent delay of the Final 340B Rule. This is particularly true since Congress, in response to several HHS OIG reports, passed a law, in 2010, directing HHS to address the very issues that are addressed in that rule. In its most recent proposed and final rule delaying the effective date of the Final 340B rule, HHS stated that it does "not believe that this delay will adversely affect any of the stakeholders in a meaningful way." 83 Fed. Reg. at 20,009; 83 Fed. Reg. at 25,944. This claim is patently wrong, has no support in the rulemaking record, and provides an additional ground for holding that the Agency's decision was arbitrary and capricious.

First, in the proposal to delay the Final 340B Rule, HHS claimed that delaying implementation of the civil money penalty rule would have no adverse effect given that more significant remedies are available to 340B providers who believe they have been overcharged by drug companies. 83 Fed. Reg. at 20,009. In response to comments that challenge this assertion on the grounds that such other significant remedies do not exist and that HHS has ignored the extent of overcharging, HHS stated that "HRSA's website describes how it carefully reviews pricing discrepancies *brought to its attention*." 83 Fed. Reg. at 25,945 (emphasis added). But HHS fails to acknowledge that relatively few discrepancies are actually brought to its attention because the parties with the greatest incentive to bring such overcharges to HRSA's attention, the 340B providers, currently do not have access to the data they need to determine if they are being overcharged. HHS never explains how its refusal to give providers access to drug ceiling prices would help it enforce the 340B law. To the contrary, the refusal adversely affects the relevant stakeholders: 340B healthcare providers.

Second, HHS claims that the delay in implementing the civil money penalty provisions will have no meaningful effect because "misreporting pricing data to CMS could lead to State and Federal False Claims Act liability." 83 Fed. Reg. at 25,945. But HHS does not provide any information regarding whether or how often such False Claims Act cases are brought to recover overcharges to 340B providers and, if so, how effective they have been in deterring such overcharges. In addition, the Supreme Court has held that 340B providers cannot sue drug companies for overcharging. *Astra USA, Inc.* v. *Santa Clara Cy., Cal.*, 563 U.S. 110, 121-22 (2011). In fact, as the OIG found, the only real remedy for overcharging that currently exists is termination from the 340B and Medicaid programs. Department of Health and Human Services Office of the Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072, at 22 (October 2005), https://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf. But such debarment would be an extraordinary measure and would have negative collateral consequences for patients and providers themselves. That is in part why OIG viewed the limited options for enforcing drug company compliance as a significant shortcoming in the 340B Program, and why the OIG recommended that HRSA seek authority to establish penalties for 340B violations. *Id.* Congress, in passing the 2010 amendments, agreed. Even if HHS's claims about False Claims Acts are correct, HHS does not explain why civil money penalties would not be an important, additional tool in enforcing the requirements of the 340B statute, as both Congress and the OIG concluded.

Third, as to enforcement of the increased discount for price increases above inflation, although HHS acknowledged that a "small number of manufacturers have informed HHS over the last several years that they charge more than $0.01 for a drug with a ceiling price below $0.01" (in violation of federal law and HHS policy), HHS stated that it "believes the *majority* of

manufacturers currently follow the practice of charging $0.01" and so the delay would "not result in a significant economic impact." 83 Fed. Reg. at 20,009; 83 Fed. Reg. at 25,945 (emphasis added).[8] HHS never even suggested, however, that it had any data to support this claim. In any event, even if it were true that a majority complies, HHS does not deny that many drug companies nonetheless are violating the law. In fact, in a July 2006 report, the OIG found that in one month, 14 percent of total purchases made by 70 sampled 340B providers exceeded the 340B ceiling prices, resulting in total overpayments of $3.9 million for the sample OIG studied; the largest overpayments resulted from inappropriate handling of prices that should have been discounted because of the inflation penalty. Department of Health and Human Services Office of the Inspector General, *Review of 340B Prices*, OEI-05-02-0073 at 11, 14 (July 2006), https://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf. The new enforcement tools could be valuable in bringing those companies into compliance.

Fourth, in response to comments submitted about the proposed delay regarding the posting of ceiling prices, HHS stated that it performs audits of drug companies, investigates all allegations of overcharging, and participates in settlements that have returned millions of dollars to 340B providers. 83 Fed. Reg. at 25,945. The implication seems to be that public posting is therefore unnecessary. These statements ignore the fact that Congress determined that making ceiling prices available to 340B providers would assist in detecting violations of the 340B law. HHS may disagree with Congress but it has no authority to ignore this Congressional directive.

[8] In June 2015 and again in February 2016, Sanofi informed HRSA that it was not following HRSA's penny pricing policy. *See* Ex. A (Letter from Robert DeBerardine, General Counsel, Sanofi North America, to Krista M. Pedley, Pharm.D. (June 10, 2015); Ex. B (Letter from Susan A. Manardo, Acting N.A. General Counsel, Sanofi, to Krista M. Pedley, Pharm.D (February 23, 2016)).

These statements are also wrong as a matter of policy. As noted above, the parties with the greatest incentive to bring such overcharges to HRSA's attention currently do not have access to the data they need to determine if they are being overcharged. Thus, relying on HRSA to act on information about such allegations is pointless. Moreover, HRSA has completed only 11 manufacturer audits since it began conducting audits in 2012. *See* "Program Integrity," https://www.hrsa.gov/opa/program-integrity/index.html. *See also Statement of Capt. Krista Pedley, PharmD, MS, Director, Office of Pharmacy Affairs, Healthcare Systems Bureau, HRSA, Before the U.S. Senate Subcommittee on Health Education, Labor and Pensions* (June 19, 2018), https://www.help.senate.gov/imo/media/doc/Pedley2.pdf ("Pedley Testimony").[9] HRSA's oversight as it existed prior to passage of the ACA (which will continue until the Final 340B Rule is implemented) already has proved to be far from adequate. That is why Congress required HHS to implement the changes in the Final 340B Rule.

Finally, HHS's statement that "it would be disruptive to require stakeholders to make potentially costly changes to pricing systems and business procedures" is absurd as to the posting of ceiling prices. 83 Fed. Reg. at 25,945. The only entity that has to make a change here is HRSA, and at a July 2017 hearing HRSA testified that it had received funding for the IT system to post ceiling prices in fiscal year 2014 and that the system would be ready in "the coming months." *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

[9] The HRSA official testified that HRSA has conducted a total of 12 audits of manufacturers since it began conducting audits in 2012. *Pedley Testimony* at 4. The website states that that number includes only audits that have been finalized; this may account for the different number. *See Program Integrity: FY17 Audit Results*, https://www.hrsa.gov/opa/program-integrity/audit-results/fy-17-results.html.

Cong., *Transcript*, at 47, 2017 WL 3104702 (Jul. 18, 2017) ("*July 2017 340B E&C Oversight Hearing Transcript*").

Because the Department's claims about the impact of delaying the 340B Final Rule have no support in the record or elsewhere, and because it failed to consider any information that would have demonstrated the actual impact such delay would have on 340B providers and their medically underserved patients, the Department's decision was arbitrary and capricious under *State Farm* and the cases cited above. *See also Stewart* v. *Azar*, 313 F. Supp. 3d 237 (D.D.C. 2018) (because the Secretary failed to consider the Medicaid waiver's impact on furnishing medical assistance – *i.e.*, providing affordable health coverage – to the low-income populations identified by Congress in the Medicaid statute, his decision was arbitrary and capricious.); *Am. Wild Horse Pres. Campaign* v. *Perdue*, 873 F.3d 914, 923 (D.C. Cir. 2017) (an agency must consider all relevant factors and record evidence).

II. HHS's Decision Delaying the Effective Date of the Final Rule Implementing the 340B Compliance Measures a Fifth Time, for an Additional Year, Was Agency Action Unreasonably Delayed in Violation of the APA.

HHS's eight-year failure to comply with the ACA by implementing the regulations at issue also violates the APA's prohibition on "unlawfully withheld or unreasonably delayed" agency action. *See* 5 U.S.C. § 706(1) (requiring courts to "compel agency action unlawfully withheld or unreasonably delayed"). The D.C. Circuit evaluates whether agency delays are unreasonable under a six-factor test, known as the "*TRAC*" factors: (1) the time agencies take to make decisions must be governed by a "rule of reason"; (2) whether there is a congressional timetable or other indication of speed with which Congress expects the agency to proceed and which may supply the basis for the "rule of reason"; (3) whether the delay is to an economic regulation, which is more tolerable than delays when human health and welfare are at stake; (4) the effect of expediting delayed action on agency priorities of a higher or competing priority;

(5) the nature and extent of the interests prejudiced by the delay; and (6) whether there was "impropriety" in the agency's delay although the court is not required to find any. *Telecomm. Research & Action Ctr. (TRAC)* v. *FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984). Each of these factors supports a finding that HHS's most recent action delaying the effective date of the Final 340B Rule is "agency action unreasonably delayed" in violation of the APA.

Rule of Reason, Congressional Timetable, or Other Indication of Speed. It has been more than eight years since Congress enacted the law that required HHS to develop and publish through an appropriate policy or regulatory issuance precisely defined standards and methodology for calculating ceiling prices, make those prices available on the HRSA website to 340B providers, and adopt standards for the imposition of civil monetary penalties. Regulations as to civil money penalties were required to be promulgated by HHS not later than 180 days after March 23, 2010. The Department's more than eight-year delay in meeting the statutory 180-day deadline for civil money penalty regulations is shockingly contrary to the Congressional timetable and to any rule of reason. *See In re Barr Lab., Inc.*, 930 F.2d 72, 75 (D.C. Cir. 1991). Even without a specific congressional timetable for the ceiling price methodology and disclosure, the more than eight-year delay in implementing those sections is not reasonable, especially because the law requires HHS to do both. *See American Academy of Pediatrics* v. *FDA*, -- F. Supp. 3d. --, No. 1:16-CV-11985-IT, 2018 WL 4232904, 2018 U.S. Dist. LEXIS 150595 (D. Mass. Sept. 5, 2018) (FDA ordered to expedite publication of a tobacco rule after missing the statutory deadline by more than seven years); *In re Pesticide Action Network N. Am., Nat. Res. Def. Council, Inc.* v. *EPA*, 798 F.3d 809 (9th Cir. 2015) (eight-year delay). The argument that the agency's delay is unreasonable is particularly compelling where the agency

has done all the work to meet the Congressional directive, namely has issued the required final rule. Thus the first and second factors weigh in favor of Plaintiffs.

Health and Human Welfare. Developing a methodology for ceiling prices and publishing them for 340B providers will ensure that such providers are not required to pay more than the appropriate amount for outpatient drugs. The threat of civil money penalties will deter drug companies from charging too much for covered drugs. Each of these three measures will ensure that 340B providers receive the savings to which they are entitled and thus ensure that they have the resources that Congress made available so they can provide critical healthcare services to communities with underserved populations that could not otherwise afford these services.

Impact of Implementing the Final 340B Rule on Agency Priorities. The regulation has already been drafted and published. No additional work is required by HHS to put it into effect. Once the regulation is in effect, HRSA's only affirmative obligations will be to publish the ceiling prices on its website, and HRSA received funding to support this effort in 2014. *July 2017 340B E&C Oversight Hearing Transcript* at 47. In fact, in the last two budget cycles HRSA identified this initiative as a priority. HRSA, *Fiscal Year 2019 Justification of Estimates for Appropriations Committees*, at 268, https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2019.pdf; HRSA, *Fiscal Year 2018 Justification of Estimates for Appropriations Committees*, at 245, https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-2018.pdf. In July 2017, HRSA said the system would be ready in "the coming months." *July 2017 E&C Oversight Hearing Transcript* at 47.

Moreover, publishing the ceiling prices could actually save HRSA resources since the providers would then have the tools to police the drug companies, taking some of that burden off

the Department. This is not a situation in which a shortage of resources is preventing the agency from accomplishing the task, and in the numerous rulemaking proceedings delaying the regulation it never suggested that this was the case.

The Interests Prejudiced by the Delay. All 340B providers are prejudiced by the delay, including the Hospital Plaintiffs, the hospital members of the Association Plaintiffs, and, by extension, their low-income patients whom Congress intended to benefit from the 340B Program. In an October 2005 report, the OIG found systemic problems with the accuracy and reliability of HRSA's record of 340B ceiling prices. Department of Health and Human Services, Office of the Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072, at 10-11 (October 2005), https://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf. The OIG recommended that HRSA establish standards for calculating 340B ceiling prices, including a methodology for calculating the ceiling price when the inflation penalty results in a ceiling price of zero or less, and that HRSA institute oversight mechanisms to validate the prices charged to covered entities. *Id.* at 21-22.[10] The delay in implementing the ceiling price methodology means that the problems with accuracy, which OIG determined resulted in overcharges, particularly with respect to application of the inflation penalty, have not been addressed and 340B providers will continue to be overcharged.[11] Thus, such providers will not be able to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" as Congress intended. H.R. REP. NO. 102-384(II), at 12 (September 22, 1992). Similarly, Congress added civil money penalties to "improve . . .

[10] As noted above, the inflation penalty can no longer result in a ceiling price of less than zero.

[11] *See* Department of Health and Human Services Office of the Inspector General, *Review of 340B Prices*, OEI-05-02-0073 at 11 (July 2006), https://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf.

compliance by manufacturers," and to "prevent overcharges and other violations of the discounted pricing requirements." 42 U.S.C. § 256b(d)(1)(A). The delay in implementing the civil money penalties provision also means that 340B providers continue to be overcharged so that they have fewer resources to devote to helping their low income patients.

Impropriety in the Agency's Delay. Although a finding of impropriety is not necessary, here HHS's blatant disregard of the statutory deadline for civil money penalties and the statutory directive to implement a ceiling price methodology and publication of ceiling prices, and its failure to provide any cogent basis for the delay, border on and arguably demonstrate agency impropriety. In *Barr* the court noted that the issue of impropriety intersects with item four's sensitivity to the agency's legitimate priorities. The Court noted that "[w]here the agency has manifested bad faith, as by . . . asserting utter indifference to a congressional deadline, the agency will have a hard time claiming legitimacy for its priorities." *Barr*, 930 F.2d at 76. Here HHS has shown utter indifference.

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As demonstrated above, all six "*TRAC*" factors support Plaintiffs' argument that HHS's failure to implement the final 340B Rule violates the APA, which permits courts to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

CONCLUSION

The Court should declare that Defendants' most recent delay of the effective date of the Final 340B Rule is arbitrary and capricious, an abuse of discretion, and contrary to law, in violation of 5 U.S.C. § 706(2)(A), and is agency action unreasonably delayed, in violation of 5 U.S.C. § 706(1). The Court should further order the Secretary to make the final 340B Rule effective within 30 days after judgment, and order fees and costs pursuant to 28 U.S.C. § 2412.

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Respectfully submitted,

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