UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION,
800 Tenth Street, NW, Suite 400
Washington, DC 20001,

AMERICA'S ESSENTIAL HOSPITALS,
401 Ninth Street, NW, Suite 900
Washington, DC 20004,

THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES,
655 K Street, NW, Suite 100
Washington, DC 20001,

340B HEALTH,
1101 15th Street, NW, Suite 910
Washington, DC 20005,

GENESIS HEALTHCARE SYSTEM,
2951 Maple Ave.
Zanesville, OH 43701,

KEARNY COUNTY HOSPITAL,
500 E. Thorpe Street
Lakin, KS 67860

RUTLAND REGIONAL MEDICAL CENTER,
160 Allen Street
Rutland, VT 05701,

Plaintiffs,

–v–

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, SW
Washington, DC 20201,

ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20201,

Defendants.

Case No. _____

COMPLAINT

Plaintiffs 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 bring this complaint against Defendants Department of Health and Human Services ("HHS") and Alex M. Azar II, in his official capacity as the Secretary of Health and Human Services and allege the following.

NATURE OF ACTION

1. This action challenges as a violation of the Administrative Procedure Act Defendants' most recent delay of the effective date of a final rule, issued in January 2017, that is designed to ensure that drug companies give hospitals that provide services for vulnerable communities, including low-income and uninsured individuals, the discounted price on prescription drugs required by federal law.

2. After Congress passed the Medicaid drug rebate program, which provides outpatient prescription drug discounts to state Medicaid agencies, it was concerned because other entities, including federally-funded clinics and public hospitals, were experiencing substantial increases in their outpatient drug costs. H.R. REP. No. 102–384(II), at 11 (1992). In 1992, Congress enacted a statute to lower those drug costs for certain public and not-for-profit hospitals, community health centers, and other federally funded clinics that serve large numbers of low-income communities in order to generate funds that they can use to serve vulnerable patients. The program was established by section 340B of the Public Health Service Act and is known as the "340B Program." The hospitals and other facilities that are approved by HHS as eligible for the program are known as "covered entities" in the statute's parlance.

3. In order to ensure that covered entities have access to drugs at lower cost, the 340B statute requires the setting of "ceiling prices": the maximum prices that drug companies

can charge to covered entities for covered outpatient drugs. By statute, the ceiling price is calculated as a rebate off the average manufacturer price (AMP), with the rebate generally equaling the greater of: (a) a minimum rebate percentage (13, 17.1 or 23.1 percent, depending on the type of drug), or (b) the difference between AMP and the "best price" the drug company has charged during the rebate period. 42 U.S.C. § 1396r-8(c)(1). For some drugs, the statute provides for a larger rebate (and thus a lower ceiling price) when a drug company has increased its drug prices faster than the rate of inflation. *Id.* § 1396r-8(c)(2)(A). By lowering the purchase costs for drugs covered by the 340B Program, Congress enabled these covered entities 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 (1992).

4. As discussed in greater detail below, through the Patient Protection and Affordable Care Act of 2010, Pub. L. 111-148, 124 Stat. 119 (March 23, 2010), as amended by section 2302 of the Health Care and Education Reconciliation Act, Pub. L. 111-152, 124 Stat. 1029, 1082 (March 30, 2010) (the "ACA"), Congress took various steps to build on the success of the 340B Program in helping covered entities serve their communities, and to cure some problems the program had faced, including the lack of transparency in ceiling prices, and the lack of robust enforcement mechanisms to ensure drug company compliance. In amending Section 340B, Congress required HHS to take various steps to "improve[] . . . compliance by manufacturers with the requirements of [Section 340B] in order to prevent overcharges and other violations of the discounted pricing requirements." ACA § 7102, 124 Stat. at 823.

5. The improvements that Congress mandated included (1) the "development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers"; (2) the implementation of "procedures for manufacturers to issue refunds to

covered entities in the event that there is an overcharge by the manufacturers"; (3) the "provision of access through the [HHS website] to the applicable ceiling prices for covered drugs as calculated and verified by the Secretary"; and (4) the "imposition of sanctions in the form of civil monetary penalties" in cases where a drug company "knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the [ceiling] price." ACA § 7102, 124 Stat. at 823-25 (codified at 42 U.S.C. § 256b(d)).

6. In September 2010, HHS issued an advanced notice of proposed rulemaking addressing the issues identified above, and then did not issue the proposed rulemaking until June 2015. HHS reopened the comment period for the proposed rule in April 2016. Those efforts culminated in January 2017 in the Department's promulgation of a final rule implementing the 2010 amendments. 82 Fed. Reg. 1210 (Jan. 5, 2017) (the "Final 340B Rule" or the "Rule"). The Final 340B Rule set an effective date of March 6, 2017.

7. In the twenty months since the Final 340B Rule was promulgated, Defendants have delayed implementation of the Rule on five separate occasions, most recently on June 5, 2018, when Defendants delayed implementation for an additional year, until July 1, 2019, 83 Fed. Reg. 25,943, 25,944 (June 5, 2018), which would delay the effective date of the final rule for 30 months from the date the Rule was issued instead of the two months that the Rule initially provided.

8. The Department's proffered rationales for their successive delays have shifted and been inconsistent, but the most frequent has been that delay has been needed to "provide affected parties sufficient time to make needed changes to facilitate compliance" – despite the passage of the statutory requirements in 2010, a proposed rule in 2015 that put parties on notice, and numerous comment periods for consideration of the very same policy that was finalized in 2017.

Id. at 25,944. That purported rationale and the others the Department has offered have no support in the administrative record or otherwise. Defendants' repeated delays are unreasonable, arbitrary and capricious, in violation of the Administrative Procedure Act ("APA").

9. Defendants' repeated delays in implementing the Final 340B Rule are causing significant harm to Plaintiffs Genesis Healthcare System, Kearny County Hospital, and Rutland Regional Medical Center (the "Hospital Plaintiffs"), and, by extension, their vulnerable patients. Defendants' actions are also causing harm to other 340B covered entities, of which there are approximately 2,487 nationwide, virtually all of which are members of Plaintiffs American Hospital Association, America's Essential Hospitals, American Association of Medical Colleges, and/or 340B Health (the "Association Plaintiffs"). The Association Plaintiffs bring this action on their behalf.

PARTIES

10. Plaintiff the American Hospital Association ("AHA") is a national, not-for-profit organization headquartered in Washington, D.C. The AHA represents and serves nearly 5,000 hospitals, health care systems, and networks, plus 43,000 individual members. Its mission is to advance the health of individuals and communities by leading, representing, and serving the hospitals, health systems, and other related organizations that are accountable to the community and committed to health improvement. The AHA provides extensive education for health care leaders and is a source of valuable information and data on health care issues and trends. It also ensures that members' perspectives and needs are heard and addressed in national health policy development, legislative and regulatory debates, and judicial matters.

11. Plaintiff America's Essential Hospitals ("AEH") is a national, not-for-profit association headquartered in Washington, D.C. AEH is a champion for hospitals and health

systems dedicated to high-quality care for all, including the most vulnerable. Since 1981, AEH has initiated, advanced, and preserved programs and policies that help these hospitals ensure access to care. Its more than 325 hospital members are vital to their communities, providing primary care through trauma care, disaster response, health professional training, research, public health programs, and other services.

12. Plaintiff Association of American Medical Colleges ("AAMC") is a national, not-for-profit association headquartered in Washington, D.C. AAMC is dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its membership consists of all 151 accredited U.S. and 17 accredited Canadian medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic societies.

13. Plaintiff 340B Health is a national, not for profit organization headquartered in Washington, D.C. The organization was founded in 1993 to advocate on behalf of 340B covered entities, and to increase the affordability and accessibility of pharmaceutical and clinical care for the nation's poor and underserved populations. 340B Health monitors, educates, and serves as an advocate on federal legislative and regulatory issues related to drug pricing and other pharmacy matters that affect safety net providers. 340B Health represents more than 1,300 public and private nonprofit hospitals and health systems that participate in the federal 340B drug pricing program.

14. Many of AHA and AAMC's member hospitals, almost all of AEH's member hospitals, and all of 340B Health's member hospitals participate in the 340B Program. Those members rely heavily on the price differential created by Congress through that Program to

generate resources that are used to provide critical health care programs for the vulnerable populations they serve.

15. Plaintiff Genesis Healthcare System ("Genesis") is an integrated health care delivery system based in Zanesville, Ohio. Genesis is the largest health care provider in its rural, economically challenged six-county region. Genesis is comprised of an acute care hospital that serves as a rural referral center and includes a 200-provider medical group and provides a multitude of ambulatory health services. Genesis is the regional safety net provider for the 235,000 residents of their six-county service area. It is a "covered entity" that participates in the 340B Program and is a member of 340B Health and the AHA.

16. Plaintiff Kearny County Hospital ("Kearny County") was founded in 1952 and has been operated as a county hospital since 1976. Kearny County provides inpatient and outpatient hospital care, emergency medicine and primary care annually to patients from 20 counties in Kansas and Colorado. Kearny County delivers approximately 350 babies per year, with one-way commutes for those patients being up to 120 miles. It is a "covered entity" that participates in the 340B Program and is a member of the AHA.

17. Plaintiff Rutland Regional Medical Center ("Rutland Regional"), headquartered in Rutland, Vermont, is also a "covered entity" that participates in the 340B Program, and is a member of 340B Health and AHA. Rutland Regional is the largest community hospital in Vermont, and the second-largest Vermont hospital overall, and has been providing high-quality healthcare for over 100 years. Rutland Regional services an aging community with a large proportion of Medicare beneficiaries.

18. Genesis, Kearny County, and Rutland Regional 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 they serve. Defendants' delay in implementation of the Final 340B Rule, which effectuates changes that Congress adopted in 2010 in response to significant findings by the HHS Office of the Inspector General of overcharging by drug companies, has threatened the ability of Genesis, Kearny County and Rutland Regional to continue to provide critical healthcare programs to their communities, including the vulnerable populations in those communities.

19. Defendant HHS is a cabinet-level department of the United States government headquartered at 200 Independence Avenue, SW, Washington, D.C. 20201. The Health Resources and Services Administration (HRSA), which is responsible for administering the 340B Program and issued the Final 340B Rule, is an agency within HHS.

20. Defendant Alex M. Azar II ("the Secretary") is the Secretary of Health and Human Services, and maintains offices at 200 Independence Avenue, SW, Washington, D.C. 20201. In that capacity, he is responsible for the conduct and policies of HHS, including the conduct and policies of HRSA. Secretary Azar is sued in his official capacity.

JURISDICTION AND VENUE

21. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331 because this action arises under the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* (the "APA"), and section 340B of the Public Health Services Act, 42 U.S.C. § 256b.

22. The APA authorizes the courts to "set aside agency action, findings, and conclusions" that are found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2), as well as agency action that has been "unreasonably delayed," *id.* § 706(1). The APA also provides a right to judicial review of all "final agency action for which there is no other adequate remedy in a court." 5 U.S.C § 704.

23. Defendants' final rules delaying implementation of the Final 340B Rule, including the June 5, 2018 Final Rule delaying the effective date of the Final 340B Rule to July 1, 2019, 83 Fed. Reg. 25943, constitute final agency actions as to which Plaintiffs are entitled to judicial review under the APA.

24. There exists an actual substantial and continuing controversy between the parties regarding the delay of the Final 340B Rule. This Court has jurisdiction to declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201–2202.

25. The Association Plaintiffs have standing because at least one of each association's members, including Genesis, Kearny County, and Rutland Regional, has been and continues to be significantly harmed by Defendants' repeated delays in implementing the Final 340B Rule. Through this lawsuit, the Association Plaintiffs seek to vindicate interests that are germane to the associations' purposes.

26. As to the ceiling price methodology, for example, the Hospital Plaintiffs and the Association Plaintiffs' members have been harmed by being charged ceiling prices calculated under inaccurate methodologies. As to the transparency-related rules, the Hospital Plaintiffs and the Association Plaintiffs' members have been deprived of access to ceiling price data, to which they are entitled under the 340B statute, as amended in 2010. Congress required that covered entities be given access to ceiling prices in part to increase drug companies' compliance with the 340B statute and because, without such access, covered entities cannot even verify whether they are being overcharged, let alone take steps to remedy such overcharging. The Hospital Plaintiffs and the Association Plaintiffs' members also have suffered harm by Defendants' failure to implement the civil monetary penalty rules because, as Congress recognized in adopting them,

civil monetary penalties likely would increase drug companies' compliance with the statute and deter them from overcharging 340B covered entities.

27. Moreover, as to each aspect of the Final 340B Rule, on information and belief, as to each Association Plaintiff, which collectively represent virtually every 340B hospital in the country, some and possibly many of the Association Plaintiffs' members have been overcharged by one or more drug companies. On information and belief, there would be fewer such overcharges if the accuracy, transparency and compliance rules set forth in the Final 340B Rule were in place. The discounts that Plaintiffs believe have been lost due to Defendants' delays could have been used to support or expand services for the vulnerable communities Plaintiffs serve, as Congress intended when it passed the 340B statute as well as the 2010 amendments.

28. Each of these injuries would be redressed by requiring Defendants to effectuate the Final 340B Rule.

29. Venue lies in this judicial district pursuant to 28 U.S.C. § 1391(e).

30. The Court has personal jurisdiction over Defendant HHS because it is an agency of the United States that resides in the District of Columbia and because a substantial part of the events that gave rise to Plaintiffs' claims occurred here. This Court has personal jurisdiction over the Defendant Secretary in his official capacity because his office is located, and a substantial part of the events giving rise to the claims occurred, in the District of Columbia.

STATUTORY AND REGULATORY BACKGROUND

A. The 340B Program

31. Congress established the 340B Program in 1992 by amending the Public Health Service Act to give hospitals, community health centers and other federally funded clinics that provide services for vulnerable communities, including low-income and uninsured individuals, a discounted price on prescription drugs. The 340B Program is administered by the Office of Pharmacy Affairs of the Healthcare Systems Bureau, a division of HRSA, which is an agency of HHS.

32. Under the 340B Program, prescription drug companies, as a condition of having their outpatient drugs be reimbursable through state Medicaid programs, are required to offer covered entities discounts calculated pursuant to a statutory formula. 42 U.S.C. § 256b(a)(1). As Congress and HRSA have recognized, the purpose of the Program is to enable eligible public and not-for-profit hospitals and other covered institutions to use their scarce resources to reach more patients, and to provide more comprehensive services.

33. Since the 340B Program was first implemented, covered entities have used the savings generated through the program to provide additional critical healthcare services for their communities, including underserved populations within those communities − for example, by providing free or discounted drugs and other services, increasing service locations, developing patient education programs, and providing translation and transportation services to improve patients' access to high-quality care.

34. Recognizing the value of the 340B Program, Congress has expanded the categories of eligible covered entities. In 1992, covered entities 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 populations. *See* 42 U.S.C. §§ 256b(a)(4)(A)-(E), (G), (L). In 2010, as a part of the ACA, in addition to making other changes to the Program to improve drug companies' compliance and to protect covered entities from overcharges, Congress expanded the definition of covered entities to include certain critical access hospitals, children's hospitals, free-standing cancer hospitals, and sole community hospitals. *See* 42 U.S.C. § 256b(a)(4)(M)-(O).

35. Genesis, Kearny County and Rutland Regional and many other members of the Association Plaintiffs are covered entities under the 340B Program.

B. The 2010 Amendments to the 340B Statute Required HHS to Improve the Accuracy and Transparency of Ceiling Prices, and to Adopt Regulations Imposing Penalties on Noncomplying Drug Companies.

36. The 340B law establishes the "ceiling price" for each drug – the maximum per-unit price that can be charged to covered entities for the drug. In the 1992 statute, Congress set forth the formula for calculating the ceiling price for a given drug. 42 U.S.C. § 256b(a). The statute sets the ceiling price as a mandatory discount from the average manufacturer price. The amount of the rebate is generally the greater of (a) a "minimum 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." 42 U.S.C. § 1396r-8(c)(1). For some drugs, the statute provides for a larger rebate (and thus lower ceiling price) when a drug company has increased its drug prices faster than the rate of inflation. *Id.* § 1396r-8(c)(2)(A).

37. Before 2010, the HHS Office of the Inspector General issued multiple reports that identified weaknesses in the oversight of the 340B Program. Congress ultimately concluded that there were several problems the statute did not adequately address. When Congress in 2010

improved the 340B Program as part of the ACA, in addition to expanding the types of hospitals that could qualify as covered entities (as noted above), it required the Department to adopt a number of measures to improve compliance with the program, including measures that would improve the accuracy and transparency of ceiling prices in several concrete ways, and would impose penalties on drug companies for noncompliance.

38. ***Accuracy***. To improve their accuracy, 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 "shall," 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). 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.*

39. ***Transparency***. Congress recognized that just bolstering the Department's tools for verifying the accuracy of ceiling prices would not be enough to improve the "[i]ntegrity" of the 340B program. More transparency was needed as well. Thus, Congress required the Secretary to give covered entities 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).

40. ***Penalties for Drug Company Noncompliance***. Congress further recognized that to "improve . . . compliance by manufacturers,"42 U.S.C. § 256b(d)(1)(A), there needed to be a threat of financial penalties to "prevent overcharges and other violations of the discounted pricing requirements." *Id.* Thus, Congress required the Secretary to impose "sanctions in the form of civil monetary penalties" against drug companies that "knowingly and intentionally" "overcharg[e] a covered entity," up to $5,000 "for each instance of overcharging." *Id.* § 256b(d)(1)(B)(vi). The amended statute also 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.*

C. HHS Issues a Final Rule Implementing the 2010 Amendments.

41. During the years following the enactment of the ACA, HHS (specifically, HRSA) issued several notices of proposed rulemaking in an attempt to comply with Congress's directives in the 2010 amendments.

42. In the process of complying with the 2010 statutory mandate, HHS also sought to address several specific matters that fell within Congress's broad directives. The 340B statute itself does not address every pricing scenario. For example, the statute does not specifically address how to calculate the ceiling price for new drugs, where there is no AMP for the "preceding" quarter, because the drug has not previously been sold. The statute also does not address what covered entities must pay when the ceiling price formula results in a price of $0, which, as noted above, can occur when a drug company increases its prices faster than the rate of inflation. *See* 42 U.S.C. § 1396r-8(c)(2)(A).

43. In June 2015, HHS issued a notice of proposed rulemaking, setting forth its proposed regulations. 80 Fed. Reg. 34,583 (June 17, 2015). The proposed rules addressed the

three problems that Congress sought to address with the 2010 amendments: accuracy, transparency, and drug company noncompliance.

44. ***Accuracy***. 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) resolving the question of what the ceiling price should be when the statutory penalty for increasing drug prices faster than inflation results in a price of $0, and (3) providing a detailed mechanism for calculating ceiling prices for new drugs. *Id.* at 34,588.

45. ***Transparency***. The proposed regulation also implemented Congress's directive to give covered entities access to ceiling prices, by providing that HRSA "will publish" those ceiling prices, rounded to two decimal places. *Id.*

46. ***Penalties for Drug Company Noncompliance***. 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.*

47. HHS received approximately 105 comments on the proposed regulations. *See* 82 Fed. Reg. 1210, 1211 (Jan. 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.

48. 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, in June 2015, with some minor modifications to account for input from some of the commenters.

49. The Final 340B Rule set an effective date of March 6, 2017. *Id.* at 1210. The Department decided, 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.*

D. Defendants' Repeated Delays of the Effective Date of the Final 340B Rule

50. The current administration took office on January 20, 2017. Defendants have not revoked the Final 340B Rule, but instead have implemented a series of postponements of the effective date of the Final 340B Rule that continue to this day.

51. ***First Delay (15 days)***. The administration first took the typical step of imposing a freeze on pending regulations. 82 Fed. Reg. 8346 (Jan. 24, 2017). That freeze extended the effective date of the Final 340B Rule by fifteen days, from March 6 to March 21, 2017. 82 Fed. Reg. 12,508 (March 6, 2017).

52. ***Second Delay (2 months)***. In March 2017, the Department 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 the following: (1) "to consider questions of fact, law, and policy raised in the rule, consistent with the 'Regulatory Freeze Pending Review' memorandum," (2) "to provide affected parties sufficient time to make needed changes to facilitate compliance," (3) to address "substantive questions raised" by the Final 340B Rule, and (4) because "we intend to engage in longer rulemaking." *Id.* at 14,333.

53. ***Third Delay (4 months)***. Two months after the Second Delay, in May 2017 the Department delayed 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.

54. ***Fourth Delay (9 months)***. When the Department proposed a fourth delay, it received nearly 100 comments, with an overwhelming majority opposing further delay. *See* 82 Fed. Reg. 45,511, 45,512 (Sept. 29, 2017). The Department nonetheless further delayed the effective date again, by another nine months, to July 1, 2018. The Department 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 on provisions of [the ACA]" on various grounds. *Id.* at 45,512-13.

55. ***Fifth and Latest Delay (12 months)***. In May 2018, HHS issued a notice of proposed rulemaking to delay the effective date another twelve months. 83 Fed. Reg. 20,009 (May 7, 2018). The Department specifically addressed the delay of the civil monetary penalties provision, claiming that delay "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 commenters submitted feedback, including pointing out the fallacy of HHS's position on civil monetary penalties, noting that covered entities "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).

56. On June 5, 2018, HHS issued its most recent final rule delaying the effective date, to July 1, 2019. *Id*. The Department reiterated some of its 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 changing environment warrants further review of the final rule and 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.

COUNT 1

VIOLATION OF THE ADMINISTRATIVE PROCEDURES ACT: ARBITRARY AND CAPRICIOUS AGENCY ACTION

57. Plaintiffs incorporate by reference paragraphs 1-56.

58. The APA requires this Court to hold unlawful any agency action that is arbitrary and capricious, an abuse of discretion, or otherwise contrary to law. 5 U.S.C. § 706(2)(A).

59. The most recent delay in implementing the Final 340B Rule, 83 Fed. Reg. 25,943 (June 5, 2018), is arbitrary and capricious, constitutes an abuse of discretion, and is contrary to law, in violation of section 706(2)(A) of the APA.

COUNT 2

VIOLATION OF THE ADMINISTRATIVE PROCEDURES ACT: AGENCY ACTION UNREASONABLY DELAYED

60. Plaintiffs incorporate by reference paragraphs 1-56.

61. The APA requires this Court to "compel agency action" that has been "unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

62. Defendants' most recent unjustified delay in implementing the Final 340B Rule, 83 Fed. Reg. 25,943 (June 5, 2018), constitutes unreasonable delay in violation of section 706(1) of the APA.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court issue judgment in their favor and against Defendants and issue the following relief:

A. A declaratory judgment that Defendants' most recent delay in implementing 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);

B. An order directing Defendants, within 30 days after judgement, to make the Final 340B Rule effective;

C. Fees and costs pursuant to 28 U.S.C. § 2412; and

D. Such other relief as this Court may deem just and proper.

Dated: September 11, 2018

Respectfully submitted,

/s/ William B. Schultz

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