THE 340B COALITION

May 22, 2018

Capt. Krista Pedley
Director
Office of Pharmacy Affairs
Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane
Mail Stop 08W05A
Rockville, MD 20857

Re: RIN 0906–AB18 - Comments on Notice of Proposed Rulemaking; Further Delay of Effective Date of 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation (submitted via Federal eRulemaking Portal: http://regulations.gov)

Dear Capt. Pedley:

On behalf of the thousands of safety-net providers enrolled in the 340B federal drug discount program, the 340B Coalition respectfully submits this letter in response to the Notice of Proposed Rulemaking published in the Federal Register on May 7, 2018.[1] The notice proposed further delaying the effective date of a Final Rule published on January 5, 2017 (Final Rule).[2] The Final Rule established regulations for the 340B ceiling price and manufacturer civil monetary penalties (CMPs) and set an effective date of March 6, 2017. The effective date of the Final Rule has already been delayed four times, and the notice proposed an additional delay to July 1, 2019. We strongly oppose any additional delay of the Final Rule because doing so will harm 340B covered entities and the patients that they serve. The Department of Health and Human Services (HHS) should implement the Final Rule immediately. The Final Rule promotes the Administration's goal of lowering drug prices. The delay is unnecessary because HHS has already spent eight years considering and responding to four separate rounds of public comments. Any further delay is contrary to federal law. HHS should implement the Final Rule now.

By letter dated September 20, 2017, we commented on the last proposed delay to the Final Rule. We have attached that letter here and incorporate it by reference because the points we raised then apply equally now. We submit the following additional comments to supplement our September 20, 2017 letter.

[1] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 20,008 (May 7, 2018).
[2] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017).

The 340B Coalition consists of thirteen national organizations representing thousands of safety-net providers and programs that participate in the 340B program. The Coalition was created to assist providers with accessing and complying with the program while working with the federal government to improve program integrity and implementation.

HHS Should Implement the Final Rule Immediately to Address 340B Overcharges and to Advance the Administration's Goal to Lower Drug Prices

Congress enacted the 340B program to enable covered entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[3] The program accomplishes this by ensuring that covered entities receive discounts on outpatient drugs. Congress, HHS, and the U.S. Supreme Court have all recognized that manufacturer overcharges have long plagued the program. The Final Rule will ameliorate this problem by creating incentives for manufacturers to comply with the law and by codifying the penny pricing rule, which serves as a disincentive for manufacturers to raise drug prices much more quickly than the rate of inflation The Final Rule thus dovetails perfectly with the Trump Administration's goal of lowering drug prices.

Manufacturers effectively raise drug prices when they fail to sell drugs to covered entities at or below the 340B ceiling price. Manufacturer overcharges have been reported repeatedly by the HHS OIG. In 2003, the OIG reviewed sales of eleven prescription drugs by five manufacturers during the one-year period ending September 30, 1999 to determine whether the manufacturers overcharged 340B covered entities.[4] The OIG determined that all five manufacturers overcharged 340B covered entities for all eleven drugs.[5] The overcharges totaled $6.1 million, which was 45% of the amount paid by covered entities during the one-year period.[6]

In 2005, the OIG issued another report that focused on "Deficiencies in the Oversight of the 340B Drug Pricing Program."[7] One of the OIG's key findings was that "HRSA lacks the oversight mechanisms and authority to ensure that 340B entities pay at or below the 340B ceiling price."[8] The OIG reported that, in 2001, the Health Resources and Services Administration (HRSA) analyzed the drug prices charged to six hospitals and "found that 37 of the 50 drug prices exceeded the ceiling price."[9] HRSA "did not pursue the issue further, citing

[3] H.R. Rep. No. 102–384(II), at 12 (1992).
[4] Dep't of Health & Human Servs. (HHS) Office of Inspector Gen. (OIG), A-06-01-00060, Pharmaceutical Manufacturers Overcharged 340B-Covered Entities 3 (2003), https://oig.hhs.gov/oas/reports/region6/60100060.pdf.
[5] *Id*.
[6] *Id*. at 3-4.
[7] HHS OIG, OEI-05-02-00072, Deficiencies in the Oversight of the 340B Drug Pricing Program (2005), https://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf.
[8] *Id*. at ii-iii, 15-17.
[9] *Id.* at 17.

insufficient authority."[10] The OIG viewed HRSA's limited options for enforcing manufacturer compliance as significant shortcomings in the 340B program. Thus, the OIG recommended that "HRSA should seek authority to establish penalties for [340B] violations."[11] Also in 2005 an OIG Deputy Inspector General testified before the House Committee on Energy and Commerce that "HRSA should seek legislative authority to impose civil monetary penalties for situations of noncompliance."[12] CMPs were necessary "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."[13]

In 2006, the OIG issued a report titled "Review of 340B Prices," which found that 14 percent of the sampled purchases made by 340B covered entities exceeded the 340B ceiling price.[14] OIG restated its recommendation that HRSA establish penalties for 340B violations by manufacturers: "it is important that HRSA have sufficient penalty authority."[15]

Following these reports and hearings, Congress added the CMP provisions to the 340B statute in 2010. A year later, the Supreme Court noted that manufacturers overcharge covered entities, and the Court emphasized the importance of the CMP provisions:

> Congress directed HRSA to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers. 124 Stat. 823–827, 42 U.S.C.A. § 256b(d). Congress thus opted to strengthen and formalize HRSA's enforcement authority, to make the new adjudicative framework the proper remedy for covered entities complaining of 'overcharges and other violations of the discounted pricing requirements,' . . . .[16]

Unfortunately, Congress's effort to "strengthen and formalize HRSA's enforcement authority" has had no effect because HRSA has not implemented the CMP provisions. In the meantime, concerns about manufacturer overcharges continue. For example, the pharmaceutical manufacturer Mylan recently entered a settlement with the federal government, under which Mylan agreed to pay $19.3 million plus interest to 340B covered entities to resolve allegations that the company overcharged entities for the drug EpiPen.[17]

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[10] *Id.*
[11] *Id*. at iv, 22.
[12] *Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce*, 109th Cong. 20 (2006) (testimony of Stuart Wright, Deputy Inspector General for Evaluation & Inspections, HHS OIG), http://www.gpo.gov/fdsys/pkg/CHRG-109hhrg30139/pdf/CHRG-109hhrg30139.pdf.
[13] *Id.*
[14] HHS OIG, OEI-05-02-00073, Review of 340B Prices i, 10 (2006), https://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf.
[15] *Id.* at ii, 20-21.
[16] *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 121-22 (2011).
[17] Settlement Agreement between United States of America and Mylan Inc. & Mylan Specialty L.P. 3 (2017), https://www.justice.gov/opa/press-release/file/990736/download.

The 340B program ensures that safety-net providers receive discount on outpatient drugs, enabling them to use savings to fund critical programs for their low-income, uninsured, and underinsured patient populations. These initiatives are imperiled by high drug costs and manufacturer overcharges. From 2010 to 2014, drug price changes alone (i.e., not accounting for growth in the volume of prescriptions) increased retail drug spending by an estimated 15 percent, twice the rate of inflation.[18] Substantial drug price increases negatively impact providers' financial health and, in turn, their ability to care for patients. It is critically important that HHS has the necessary tools to ensure manufacturers are not overcharging covered entities.

An October 2016 National Opinion Research Center (NORC) report on price increases elaborates on the impact:

> [P]rice increases are extremely troublesome throughout the health care system. They not only threaten patient access to drug therapies, but also challenge providers' abilities to provide the highest quality of care. Drug costs also are a major factor in the rising cost of health care coverage. Hospitals bear a heavy financial burden when the cost of drug increases and must make tough choices about how to allocate scarce resources. . . . Managing these skyrocketing cost increases forces difficult choices between providing adequate compensation to employees, many of whom are highly skilled in professions facing shortages; upgrading and modernizing facilities; purchasing new technologies to improve care; or paying for drugs, especially when these price increases are not linked to new therapies or improved outcomes for patients.[19]

"The President has consistently emphasized the need to reduce the price of prescription drugs."[20] The Final Rule will not only strengthen the 340B program, but also further the Administration's goal of controlling drug costs. It will give HHS an effective penalty to impose on manufacturers that overcharge covered entities and to deter other manufacturers from doing so. The Final Rule will codify and reinforce HHS's longstanding penny pricing policy that disincentivizes manufacturers from increasing drug prices much more quickly than the rate of inflation. For these reasons, HHS should not delay the Final Rule for another year.

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[18] HHS, Office of the Assistant Sec'y for Planning & Evaluation, Observations on Trends in Prescription Drug Spending, 5 (2016), https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf.

[19] NORC at the Univ. of Chi., Trends in Hospital Inpatient Drug Costs: Issues and Challenges, Preface (2016), http://www.aha.org/content/16/aha-fah-rx-report.pdf.

[20] Exec. Office of the President, 2019 Budget Fact Sheet, Lower the Price of Drugs by Reforming Payments, https://www.whitehouse.gov/wp-content/uploads/2018/02/FY19-Budget-Fact-Sheet_Reforming-Drug-Pricing-Payment.pdf.

Any Additional Delay Could Result in Further Delay of the Ceiling Price Database, Leaving Covered Entities without Access to Ceiling Prices

A major deficiency in the 340B program from the beginning has been the lack of information on 340B ceiling prices. The program cannot function as intended if covered entities cannot determine whether manufacturers charge prices in compliance with the law. HHS has long recognized this problem. The OIG found that covered entities cannot independently verify that they receive the correct 340B discount.[21] The OIG recommended that CMS and HRSA work together to ensure accurate and timely pricing data for the government's official record of 340B ceiling prices.[22] The Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce held a hearing on the 340B program in which the Chairman, Ed Whitfield, stated, "It is nonsensical to me that the entities entitled to the 340B discount . . . do not have access to the ceiling prices."[23]

To address this deficiency in the program, Congress mandated in 2010 that HHS publish on its website a database of ceiling prices that is accessible to covered entities.[24] As of the date of these comments, the required database is still not operational and is long overdue. HRSA's recent budget justification for Fiscal Year 2019 stated that database "[i]mplementation is expected once the Civil Monetary Penalty and Ceiling Price calculation regulation has been finalized and any necessary change to the system have been implemented."[25] We are very concerned that further delay of the Final Rule could result in additional postponement of the database. 340B covered entities require this basic information so that they can be assured that they are being charged appropriately.

Contrary to the HHS's Statements in the Notice, There Is No Evidence That Manufacturer Compliance with the Penny Pricing Policy Has Improved

HHS states in the proposed rule that it "believes the majority of manufacturers currently follow" the penny pricing policy.[26] HHS does not explain the basis for this belief, and it is contrary to the findings of government reports. In a 2006 report, the HHS OIG found that 14 percent of the sampled purchases made by 340B entities exceeded the 340B ceiling price.[27] The

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[21] HHS OIG, OEI-05-02-00072, Deficiencies in the Oversight of the 340B Drug Pricing Program iii, 18 (2005), https://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf.
[22] *Id*. at iii, 21.
[23] *Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce*, 109th Cong., 2 (2006) (testimony of Stuart Wright, Deputy Inspector General for Evaluation & Inspections, HHS OIG), http://www.gpo.gov/fdsys/pkg/CHRG-109hhrg30139/pdf/CHRG-109hhrg30139.pdf.
[24] 42 U.S.C. § 256b(d)(1)(B)(iii).
[25] HHS Fiscal Year 2019 HRSA Justification of Estimates for Appropriations Committees 269, https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2019.pdf.
[26] 83 Fed. Reg. at 20,009.
[27] HHS OIG, OEI-05-02-00073, Review of 340B Prices i-ii (2006), https://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf.

largest overcharges were due to manufacturers' failure to comply with HHS's penny pricing policy.[28] In a 2003 report, the OIG determined that five manufacturers overcharged covered entities for eleven drugs.[29] One of the drugs for which covered entities were overcharged should have had a 340B ceiling price of a penny.[30] Further, one of the undersigned organizations has heard manufacturer attorneys state that manufacturers need not follow the penny pricing guidance, asserting that it is "voluntary."

Until the penny pricing policy is codified in a regulation, there is less incentive for manufacturers to comply with the policy. HHS should implement the Final Rule so that manufacturers will have to comply with this reasonable policy.

Delaying the Final Rule Leaves Covered Entities with No Recourse When Manufacturers Do Not Comply With 340B Program Requirements

In the proposed rule, HHS asserts that "delaying implementation of the 340B-specific CMPs 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 that they are entitled to receive under the program."[31] HHS does not identify these "other more significant remedies." In fact, no such remedies exist. Covered entities are not permitted to audit manufacturers. HHS's current dispute resolution process is voluntary, and manufacturers do not have to participate. HHS proposed a mandatory dispute resolution process, but withdrew the proposal.[32] In *Astra, USA, Inc. v. Santa Clara County*, the Supreme Court held that 340B covered entities cannot sue the manufacturers for overcharges under the theory that the facilities are third-party beneficiaries of the 340B Pharmaceutical Pricing Agreement between manufacturers and the Secretary of HHS.[33]

Thus, the covered entities will have no remedy when manufacturers charge above the 340B ceiling price until the CMP rule become effective. Covered entities cannot fulfill their vital mission to help America's low-income, uninsured, and underinsured patients if manufacturers overcharge covered entities for 340B drugs. Any further postponement of the regulations would frustrate Congress's intent that HHS has meaningful oversight and enforcement authority and harm 340B covered entities and their patients.

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[28] *Id.*
[29] HHS OIG, A-06-01-00060, Pharmaceutical Manufacturers Overcharged 340B-Covered Entities 3 (2003), https://oig.hhs.gov/oas/reports/region6/60100060.pdf.
[30] *Id.*
[31] *Id*.
[32] 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381 (Aug. 12, 2016) (proposed rule). This proposed rule was withdrawn on August 1, 2017. Office of Mgmt. & Budget, Exec. Office of the President, View Rule, 340B Drug Pricing Program; Administrative Dispute Resolution Process, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AA90.
[33] *Astra USA, Inc.*, 563 U.S. at 118-21.

HHS's Delay of the Final Rule Is Contrary to Law

The Final Rule is long overdue. On January 5, 2017, HHS finally issued the rule, nearly seven years after the underlying statute was enacted. The Final Rule was to be effective on March 6, 2017. HHS is violating Congress's deadline for the CMP provisions, and HHS should not delay the Final Rule until July 1, 2019. Any further postponement of other aspects of the rule would constitute agency action "unlawfully withheld or unreasonably delayed" under the Administrative Procedure Act (APA).[34] HHS should make the Final Rule effective immediately.

I. Any Delay of the CMP Provisions Violates the 340B Statute

As we explained in our September 20, 2017 letter, HHS's delay of the Final Rule violates the deadline for CMP provisions that Congress set in the 340B statute. In clear and unambiguous language, Congress required HHS to impose "sanctions in the form of civil monetary penalties, *which shall be assessed according to standards established in regulations to be promulgated by the Secretary* ***not later than 180 days after March 23, 2010*** *. . . .*"[35] Congress gave HHS 180 days from March 23, 2010 to issue CMP provisions, making the deadline September 19, 2010.[36] Because HHS has missed its statutory deadline, the current delay and any further delay are contrary to law. HHS has no authority under the 340B statute to delay the effective date of the CMP provisions.

HHS has not complied with the statutory directive to promulgate CMP provisions by September 19, 2010. The key factor in determining "whether a regulatory action constitutes promulgation of a regulation" is "whether the action has binding effects on private parties or on the agency."[37] HHS has not promulgated a regulation as required by the statute because the Final Rule is not yet binding on private parties and HHS. HHS has violated the statute, and will continue to violate the statute, until it puts into effect the provisions establishing standards for assessing CMPs on "any manufacturer with [a Pharmaceutical Pricing Agreement] that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds" the 340B ceiling price.[38]

II. Any Further Delay of the Final Rule's Other Provisions, Including the Penny Pricing Policy, Violates the APA

HHS's failure to meet the other statutory requirements enacted in 2010 is also contrary to law. Although the statute imposed no deadline for the developing precisely defined standards for determining ceiling prices (e.g., penny pricing), HHS's eight-year failure to comply

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[34] 5 U.S.C. § 706(1).
[35] 42 U.S.C. § 256b(d)(1)(B)(vi)(I) (emphasis added).
[36] *Id.*
[37] *Molycorp, Inc. v. EPA*, 197 F.3d 543, 545 (D.C. Cir. 1999).
[38] 42 U.S.C. § 256b(d)(1)(B)(vi).

with the statute is unreasonable and violates the APA, which permits a court to "compel agency action unlawfully withheld or unreasonably delayed."[39]

The D.C. Circuit evaluates agency delays 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) a congressional timetable may supply the basis for the "rule of reason;" 3) delays in economic regulation are more tolerable than delays when human health and welfare are at stake; 4) the court should consider the effect of expediting delayed action on agency priorities; 5) the court should also take into account the nature and extent of the interests prejudiced by the delay; and 6) the court is not required to find any "impropriety" in the agency's delay.[40] No single factor is dispositive, and a court will weigh the factors against each other. Although *TRAC* involved a writ of mandamus (i.e., an order for an agency to comply), the same test applies to agency delay under the APA.[41]

These factors show that HHS's failure to comply with the statute violates the APA. Congress imposed these mandates more than eight years ago, and HHS's noncompliance is contrary to any "rule of reason." The 340B program impacts the health and welfare of the nation's most vulnerable patients who are served by covered entities. The fourth *TRAC* factor is easily met because HHS has already promulgated the rule. Thus, implementing it will deplete none of HHS's resources and will impact none of its other priorities. The interests prejudiced by the delay include the public's interest in HHS complying with the law and the interest of covered entities in receiving the discounts to which they are entitled. HHS should delay the Final Rule no further.

Conclusion

We believe that the Final Rule is crucial to codify important 340B policies and to ensure that manufacturers comply with 340B program requirements. We urge HHS to implement the Final Rule immediately. We thank HHS for the opportunity to comment on the proposed delay. If you have any questions or need additional information, please do not hesitate to reach out to any of the individuals in the attached list of organizational contacts.

Sincerely,

The 340B Coalition

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[39] 5 U.S.C. § 706(1).

[40] *Telecomm. Research & Action Ctr. v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984); *see also Am. Hosp. Ass'n. v. Burwell*, 812 F.3d 183, 189 (D.C. Cir. 2016).

[41] *See Biodiversity Legal Found. v. Badgley*, 309 F.3d 1166, 1177 (9th Cir. 2002); *see also Carpet, Linoleum & Resilient Tile Layers, Local Union No. 419, Bhd. of Painters & Allied Trades, AFL-CIO v. Brown*, 656 F.2d 564, 567 (10th Cir. 1981) (section 706(1) of the APA "is essentially in the nature of mandamus.").

Organizational Contacts

Colleen Meiman
Director of Regulatory Affairs
National Association of Community Health Centers
202-296-0158; cmeiman@ncachc.org

Joe Pugliese
President
The Hemophilia Alliance
215-439-7173; joe@hemoalliance.org

Murray Penner
Executive Director
National Alliance of State & Territorial AIDS Directors
202-434-8090; mpenner@nastad.org

Stephanie Arnold Pang
Director, Policy and Government Relations
National Coalition of STD Directors
202-715-42865; sarnold@ncsddc.org

Andrea Weddle
Executive Director
HIV Medicine Association
703-299-0915; aweddle@hivma.org

Brian Bowden
Associate Legislative Director, Health
National Association of Counties
202-942-4275; bbowden@naco.org

Diane Calmus
Regulatory Counsel
National Rural Health Association
202-639-0550 ext. 2075; dcalmus@nrharural.org

Steven Chen
Manager, Policy Analysis
Children's Hospital Association
202-753-5382; steven.chen@childrenshospitals.org

Beth Feldpush
Senior Vice President, Policy and Advocacy
America's Essential Hospitals
202-585-0111; bfeldpush@essentialhospitals.org

Greg Doggett
Vice President, Legal and Policy Counsel
340B Health
202-552-5859; greg.doggett@340bhealth.org

THE 340B COALITION

September 20, 2017

Capt. Krista Pedley
Director
Office of Pharmacy Affairs
Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane
Mail Stop 08W05A
Rockville, MD 20857

Re: RIN 0906-AB11 - Comments on Notice of Proposed Rulemaking; Further Delay of Effective Date of 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation (submitted via Federal eRulemaking Portal: http://regulations.gov)

Dear Capt. Pedley:

On behalf of the thousands of safety-net providers enrolled in the 340B federal drug discount program, the 340B Coalition, joined by Ryan White Clinics for 340B Access, respectfully submits this letter in response to the Notice of Proposed Rulemaking published in the Federal Register on August 21, 2017.[1] The notice proposed further delaying the effective date of a Final Rule published on January 5, 2017.[2] The Final Rule established regulations for the 340B ceiling price and manufacturer civil monetary penalties (CMPs) and set an effective date of March 6, 2017. The effective date of the Final Rule has already been delayed three times, and the notice proposed an additional delay to July 1, 2018. We strongly oppose additional delay of the Final Rule because doing so will harm 340B covered entities and the patients that they serve. Further delay also is unnecessary because the Health Resources and Services Administration (HRSA) has already spent seven years considering and responding to stakeholder input, including four separate rounds of public comments. In addition, further delay is contrary to federal law. We urge the Department of Health and Human Services (HHS) to implement the Final Rule immediately.

The 340B Coalition consists of twelve national organizations representing thousands of safety-net providers and programs that participate in the 340B program. The Coalition was created to assist providers with accessing and complying with the program while working with the federal government to improve program implementation and quality.

[1] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 39,553 (Aug., 21, 2017).
[2] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017).

Background

Manufacturer overcharges have long plagued the 340B program. The HHS Office of the Inspector General (OIG) issued three reports in the mid-2000s detailing this problem. In 2003, the OIG issued a report titled "Pharmaceutical Manufacturers Overcharged 340B-Covered Entities" that reviewed sales of eleven prescription drugs by five manufacturers during the one-year period ending September 30, 1999 to determine whether the manufacturers overcharged 340B covered entities.[3] The OIG determined that 100% of manufacturers overcharged 340B covered entities for all eleven drugs.[4] The OIG estimated these overcharges, which totaled $6.1 million, represented 45% of the amount paid by covered entities during the one-year period.[5]

In 2005, the OIG issued a report titled "Deficiencies in the Oversight of the 340B Drug Pricing Program" that focused on HRSA's administration and oversight of the 340B program and included numerous findings and recommendations for improvements. The OIG found systemic problems with the accuracy and reliability of HRSA's record of 340B ceiling prices. In particular, HRSA's record of the 340B ceiling prices for the first quarter of 2005 was missing 28% of the 340B ceiling prices, and 8% of the prices did not include the 340B discount.[6] The OIG found that HRSA lacked the oversight mechanisms and authority to ensure that 340B entities pay at or below the 340B ceiling price.[7] Participating entities could not independently verify that they receive the correct 340B discount.[8]

The OIG recommended that the Centers for Medicare and Medicaid Services (CMS) and HRSA work together to ensure accurate and timely pricing data for the government's official record of 340B ceiling prices.[9] The OIG determined that HRSA should establish detailed standards for calculating 340B ceiling prices, including specifying package sizes and a conversion factor for negative ceiling prices.[10] The OIG viewed HRSA's limited options for enforcing manufacturer compliance as significant shortcomings in the 340B program. Thus, the OIG recommended that HRSA seek authority to establish penalties for 340B violations.[11]

In response to these OIG reports, the House Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce held a hearing in 2005 on oversight

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[3] Department of Health and Human Services (HHS) Office of Inspector General (OIG), Pharmaceutical Manufacturers Overcharged 340B-Covered Entities 3 (Mar. 10, 2003), https://oig.hhs.gov/oas/reports/region6/60100060.pdf.
[4] *Id*.
[5] *Id*. at 3-4.
[6] HHS OIG, Deficiencies in the Oversight of the 340B Drug Pricing Program ii, 10-11, (Oct. 2005), https://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf.
[7] *Id*. at ii-iii, 15-17.
[8] *Id*. at iii, 18.
[9] *Id*. at iii, 21.
[10] *Id*. at iii, 21.
[11] *Id*. at iv, 22.

and administration of the 340B program.[12] Stuart Wright, the OIG Deputy Inspector General for Evaluation and Inspections, testified that "HRSA should seek legislative authority to impose civil monetary penalties for situations of noncompliance."[13] CMPs were necessary "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."[14]

In 2006, the OIG issued a report titled "Review of 340B Prices," which found that 14 percent of the sampled purchases made by 340B covered entities exceeded the 340B ceiling price.[15] OIG expressed continued support for its recommendation that HRSA establish penalties for 340B violations by manufacturers, noting "it is important that HRSA have sufficient penalty authority."[16]

Congress responded in 2010 by enacting several important revisions to the 340B statute.[17] As amended, the statute requires the Secretary of HHS to implement certain "improvements in program integrity" for the 340B program.[18] These improvements include a directive for HHS to issue regulations for determining manufacturer ceiling prices and for imposing CMPs on manufacturers that "knowingly and intentionally" charge covered entities more than the ceiling price for covered outpatient drugs. The statute expressly requires HHS to promulgate CMP regulations not later than 180 days after March 23, 2010.[19] That 180-day deadline fell on September 19, 2010.

HHS did not meet the deadline. A day after the deadline, on September 20, 2010, HRSA issued an Advance Notice of Proposed Rulemaking (ANPRM) "to obtain information and public comment on how to efficiently and effectively implement the civil monetary penalties" required by the statute.[20] The ANPRM did not promulgate CMP standards but instead sought input. Five years later, on June 17, 2015, HRSA issued a notice of proposed rulemaking for 340B ceiling prices and the imposition of CMPs on manufacturers under the 340B program.[21] The public comment period for the June 17, 2015 proposed rule closed on August 17, 2015, and HRSA received 35 comments.[22] On April 19, 2016, HRSA reopened comments on the proposed

[12] Oversight and Administration of The 340B Drug Discount 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).
[13] *Id.* at 20.
[14] *Id.*
[15] HHS OIG, Review of 340B Prices i, 10 (July 2006), https://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf.
[16] *Id.* at ii, 20-21.
[17] Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, § 7102, 124 Stat. 823 (2010) (amending Public Health Service Act § 340B(d), 42 U.S.C. § 256b(d)).
[18] 42 U.S.C. § 256b(d).
[19] *Id.* at § 256b(d)(1)(B)(vi)(I).
[20] 340B Drug Pricing Program Manufacturer Civil Monetary Penalties, 75 Fed. Reg. 57,230 (Sept. 20, 2010).
[21] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 80 Fed. Reg. 34,583 (June 17, 2015).
[22] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210, 1,211 (Jan. 5, 2017).

rule and sought additional comments on three areas: 1) HRSA's "penny price" policy for ceiling prices that are less than $0.01; 2) estimating ceiling prices for new drugs and 3) the definition of "knowing and intentional" for purposes of manufacturer CMPs.[23] This second comment period closed on May 19, 2016, and HHS received 70 comments.[24] On January 5, 2017, HRSA finalized the regulations with an effective date of March 6, 2017.[25] HRSA stated that it would begin enforcing the Final Rule on April 1, 2017.

The Final Rule was a major step forward toward holding drug manufacturers accountable for ensuring that covered entities are offered covered outpatient drugs at a price that does not exceed the 340B ceiling price. The Final Rule adopted the statutory formula for calculating the 340B ceiling price of a drug. HRSA codified its longstanding policy by setting a price of one cent when the 340B ceiling price is less than a penny, which can occur when the price of a drug increases significantly more quickly than the rate of inflation. HRSA adopted a revised methodology for setting prices for new drugs. Finally, HRSA complied with the statute's requirement to promulgate regulations establishing standards for assessing CMPs when manufacturers knowingly and intentionally overcharge covered entities for covered outpatient drugs.

On January 20, 2017, the Assistant to the President and Chief of Staff issued a "Memorandum for the Heads of Executive Departments and Agencies" requesting a "Regulatory Freeze Pending Review."[26] Paragraph 3 of the Assistant to the President's memorandum asked agencies, where "permitted by applicable law," to delay for 60 days the effective date of regulations that had been published in the Federal Register but had not yet taken effect.[27] The memorandum also requested "[w]here appropriate and as permitted by applicable law" that agencies "should consider proposing for notice and comment a rule to delay the effective date for regulations beyond that 60-day period."[28] Paragraph 4 of the memorandum stated that agencies should "[e]xclude from the actions requested in paragraphs 1 through 3 any regulations subject to statutory or judicial deadlines and identify such exclusions to the OMB Director as soon as possible."[29]

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[23] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation; Reopening of Comment Period, 81 Fed. Reg. 22,960 (Apr. 19, 2016).
[24] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210, 1,211 (Jan. 5, 2017).
[25] *Id.* at 1,201.
[26] White House Memorandum for the Heads of Executive Departments and Agencies Regarding Regulatory Freeze Pending Review (Jan. 20, 2017), https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies).
[27] *Id.*
[28] *Id.*
[29] *Id.*

In response to the Assistant Director's memorandum, HRSA published a notice on March 6, 2016 that delayed the Final Rule until March 21, 2017.[30] On March 20, 2017, HRSA issued an Interim Final Rule (IFR) further delaying the Final Rule until May 22, 2016 and requesting comments on a possible additional delay until October 1, 2017.[31] On May 19, 2017, HRSA delayed the Final Rule until October 1, 2017.[32] On August 21, 2017, HRSA requested comments on a potential additional delay until July 1, 2018.[33]

The Final Rule Should Be Implemented Immediately to Protect Covered Entities from Manufacturer Overcharges That Undermine the 340B Program and Harm Safety-Net Providers and Their Patients

The 340B program provides crucial relief from high drug prices to safety-net providers that rely on 340B savings to fund critical programs for their low-income, uninsured, and underinsured patient populations. These initiatives are imperiled by skyrocketing drug costs and manufacturer overcharges. From 2010 to 2014, drug price changes alone (i.e., not accounting for growth in the volume of prescriptions) increased retail drug spending by an estimated 15 percent, twice the rate of inflation.[34] Substantial drug price increases negatively impact providers' financial health and, in turn, their ability to care for patients.[35] Therefore, it is critically important that HRSA have the necessary tools to ensure manufacturers are not overcharging covered entities.

Adequate enforcement of manufacturers' pricing obligations is key to the success of the 340B program, which is intended to allow covered entities to save money on drug purchases so that they can "reach[] more . . . patients" and furnish "more comprehensive services."[36] Multiple reports and national data demonstrate that the 340B program is used by hospitals that

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[30] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties; Delay of Effective Date, 82 Fed. Reg. 12,508 (Mar. 6, 2017).
[31] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 14,332 (Mar. 20, 2017).
[32] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 22,893 (May 19, 2017).
[33] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 39,553 (Aug., 21, 2017).
[34] HHS, Office of the Assistant Secretary for Planning and Evaluation, Observations on Trends in Prescription Drug Spending, 5 (Mar. 8, 2016), https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf.
[35] An October 2016 NORC report on price increases elaborates on this impact: "[P]rice increases are extremely troublesome throughout the health care system. They not only threaten patient access to drug therapies, but also challenge providers' abilities to provide the highest quality of care. Hospitals bear a heavy financial burden when the cost of drug increases and must make tough choices about how to allocate scarce resources. … Managing these skyrocketing cost increases forces difficult choices between providing adequate compensation to employees, many of whom are highly skilled in professions facing shortages; upgrading and modernizing facilities; purchasing new technologies to improve care; or paying for drugs, especially when these price increases are not linked to new therapies or improved outcomes for patients." NORC, Trends in Hospital Inpatient Drug Costs: Issues and Challenges, Preface (Oct. 2016), http://www.aha.org/content/16/aha-fah-rx-report.pdf.
[36] H.R. Rep. 102-384, 102d Cong., pt.2, at 12 (2d Sess. 1992).

provide a high level of care to low-income patients. 340B disproportionate share (DSH) hospitals treat 64 percent more Medicaid and low-income Medicare patients than non-340B hospitals.[37] Although 340B DSH hospitals account for only 36 percent of all Medicare acute care hospitals, they provide nearly 60 percent of all uncompensated care.[38] 340B DSH hospitals are also significantly more likely than non-340B hospitals to offer vital health care services that are often unreimbursed, including trauma centers, HIV/AIDS services, and immunizations.[39] Compared to non-340B providers, 340B DSH hospitals treat many more Medicare Part B beneficiaries who are low-income cancer patients, dually eligible for Medicaid, disabled, have end stage renal disease, or are racial or ethnic minorities.[40] Rural hospitals also rely on 340B savings, given the financial struggles they face. Eighty rural hospitals have closed since 2010 and more are squeezed by reduced reimbursements and rising healthcare costs.[41]

Many covered entities rely on their 340B program savings to meet the needs of their low-income patients. For example, one 340B hospital participant uses 340B savings to fund financial navigators who assist newly diagnosed cancer patients in locating and applying for resources such as grants, Medicaid, and drug manufacturer patient assistance programs. The navigators collaborate with patients to address their financial concerns so they can focus on their health and well-being. We know of another covered entity that uses 340B savings to provide free outreach clinics to the Amish community, which is uninsured and geographically and culturally isolated. A covered entity uses 340B savings to employ a Patient Assistance/Indigent Coordinator who helps ensure that indigent cancer patients are able to achieve their life-saving chemotherapy regimens. Savings from the 340B program support a comprehensive Language Access and Communication Service Center, the first of its kind in the nation, that assists patients with hearing or sight impairment, literacy issues, or limited English proficiency to navigate the healthcare system.

340B discounts also support a discharge counseling program that integrates a pharmacist into patients' discharge planning to augment the transition of care. Yet another example is an antimicrobial stewardship program that allows a pharmacist to review antibiotic regimens for appropriateness and safety to prevent the unnecessary use of antibiotics to stem

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[37] Dobson Davanzo & Associates, Update to a 2012 Analysis of 340B Disproportionate Share Hospital Services Delivered to Vulnerable Patient Populations Eligibility Criteria for 340B DSH Hospitals Continue to Appropriately Target Safety Net Hospitals (Nov. 15, 2016), http://www.340bhealth.org/files/Update_Report_FINAL_11.15.16.pdf.

[38] *Id.*

[39] *Id.*

[40] Dobson DaVanzo, Analysis of the Proportion of 340B DSH Hospital Services Delivered to Low-Income Oncology Drug Recipients Compared to Non-340B Provider (2017), http://www.340bhealth.org/files/LowIncomeOncology.pdf; Dobson DaVanzo, Analysis of Patient Characteristics among Medicare Recipients of Separately Billable Part B Drugs from 340B DSH Hospitals and Non-340B Hospitals and Physician Offices (Nov. 15, 2016), http://www.340bhealth.org/files/Demographics_Report_FINAL_11.15.2016.pdf.

[41] NC Rural Health Research Program, 80 Rural Hospital Closures: January 2010 – Present, http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.

the incidence of antibiotic-resistant microbes. The program enables covered entities to provide take-home medication packages for patients in rural areas to provide them with treatment until pharmacies are open. Savings from the program support underfunded home infusion and anticoagulation clinics services.

340B savings are particularly important to non-hospital covered entities that are often small and operate on modest budgets. One Ryan White grantee uses the savings to meet the goals of the National HIV/AIDS Strategy 2020[42] by providing specialized and primary medical services, dental care and other services to people living with HIV/AIDS. Another Ryan White grantee uses lower 340B drug costs to enable a program for children and families that provides tutoring, mentoring, life skills, child and family advocacy, and other support services to HIV-positive children, youth, and parents. Many of these services are not reimbursed by any payer and would not be available without the savings offered by the 340B program. A Ryan White clinic uses the savings to assist patients with financial hardships that interfere with treatment regimens, such as transportation difficulties, housing crises, or other struggles.

Federally Qualified Health Centers use the savings from the 340B program to provide free or heavily discounted medications to indigent, underinsured or uninsured patients under 200% of the federal poverty level. Savings from the 340B program support a wide range of services in their communities, including but not limited to opioid treatment services, clinical pharmacy services, increased access to dental services, home visits, and expanded hours.

Comprehensive hemophilia treatment centers use 340B program savings to maintain and expand clinical services for all bleeding disorders patients seen at their centers. These services include non-reimbursable services like coordination of care with primary care physicians, social work services and physical therapy assessments as well as rural outreach clinics where the centers bring care to the patients who are otherwise unable to travel to the clinic.

The safety-net missions of 340B providers are significantly undermined by manufacturer overcharges. The problem of overcharges has been recognized both by Congress, HHS, and the U.S. Supreme Court. The CMP provision grew from congressional hearings in 2005 in response to OIG reports documenting manufacturer overcharges and HRSA's inability to impose sanctions. One of those reports, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, found that "HRSA lacks the oversight mechanisms and authority to ensure that 340B entities pay at or below the 340B ceiling price."[43]

In a 2011 U.S. Supreme Court case, *Astra, USA, Inc. v. Santa Clara County, Cal.*, the 340B Coalition filed an amicus brief discussing the OIG's findings that manufacturers overcharge

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[43] HHS OIG, Deficiencies in the Oversight of the 340B Drug Pricing Program, ii (Oct. 2005), http://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf.

covered entities millions of dollars per year. The 340B Coalition argued that the CMP provisions represent a fundamental reform that will improve HRSA's enforcement capabilities. The Supreme Court agreed, noting that manufacturers overcharge covered entities, and the Court emphasized the importance of the CMP provisions in which "Congress thus opted to strengthen and formalize HRSA's enforcement authority . . ." as a critical check on manufacturers.[44]

Since 2010, Congress has granted HHS CMP authority to provide it with the necessary oversight. HHS should not delay implementation of the CMP provisions further because manufacturer overcharges are a serious and ongoing problem that undermines the integrity of the 340B program. For example, pharmaceutical manufacturer Mylan recently entered a settlement with the federal government, under which Mylan agreed to pay $19.3 million plus interest to 340B covered entities to resolve allegations that the company overcharged entities for the drug EpiPen.[45] The Mylan settlement is just the most recent example in a long history of settlements that included payments to covered entities to address alleged 340B overcharges.[46]

Covered entities cannot fulfill their vital missions to help America's low-income, uninsured and underinsured patients if manufacturers overcharge covered entities for 340B drugs. Any postponement of the regulations would frustrate Congress's intent that HRSA have meaningful oversight and enforcement authority.

Further Delays Are Unnecessary Because HRSA Has Already Spent Seven Years Considering and Responding to Stakeholder Comments

More than seven years have passed since Congress added the CMP provision to the 340B statute, and HHS missed its statutory deadline for promulgating the Final Rule by more than six years. HRSA has been soliciting public input on the CMP requirements and related provisions since that time, but they have still not been implemented. No possible benefit can come from a further delay in the Final Rule because all stakeholders have had ample opportunity to express their concerns, and those concerns have been considered by HRSA and incorporated into the Final Rule where appropriate.

I. The Final Rule Has Gone through Extensive Consideration and Comment

After Congress added the CMP provision, HRSA issued the ANPRM to seek stakeholder input so that HRSA could develop CMP and ceiling price regulations.[47] HRSA then spent almost five years considering that input and finally issued a notice of proposed rulemaking in June 2015.[48] HRSA received 35 comments totaling 283 pages.[49] Several organizations in the 340B

[44] Astra USA, Inc. v. Santa Clara County, Cal., 563 U.S. 110, 121-22 (2011).
[45] Settlement Agreement 3, https://www.justice.gov/opa/press-release/file/990736/download.
[46] See Attachment titled "Medicaid Rebate Settlements with 340B Repayments."
[47] 340B Drug Pricing Program Manufacturer Civil Monetary Penalties, 75 Fed. Reg. 57,230 (Sept. 20, 2010).
[48] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 80 Fed. Reg. 34,583 (June 17, 2015).

Coalition submitted a joint comment letter, and that letter comprehensively expressed the views of the covered entity community. A wide array of manufacturers and groups representing manufacturers submitted 18 comments, totaling 220 pages—these groups included the Coalition for Government Procurement, PhRMA, Purdue, Bayer Healthcare, Lilly, AbbVie, Teva Pharmaceuticals, the National Council for Prescription Drug Programs, GlaxoSmithKline, Sanofi, Grifols, BIO, Mallinckrodt Pharmaceuticals, Pfizer, Johnson & Johnson, the Medicines Company, Astellas, and Novartis. These groups commented on all aspects of the proposed rule, including the calculation of the ceiling price, the penny pricing rule, and the CMP procedures.

HRSA then reopened the comment period on April 19, 2016, on three issues: 1) the penny price policy; 2) estimation of ceiling prices for new drugs; and 3) the definition of "knowing and intentional" for purposes of manufacturer CMPs.[50] This comment period closed on May 19, 2016, and HHS received 70 comments, totaling 385 pages.[51] The 340B Coalition submitted comments on behalf of covered entities, as did many other groups and individual covered entities. HRSA received nine comment letters totaling 166 pages from manufacturers or groups representing manufacturers, which included Bristol-Myers Squibb, PhRMA, EMD Serono, Bayer Corporation, Sanofi, Recordati Rare Diseases, Teva Pharmaceuticals, Lilly, and BIO. Two of these entities—Bristol-Myers Squib and Recordati Rare Diseases—did not submit comments during the first comment period. Again, manufacturer groups expressed views on all aspects of the three issues for which HRSA sought additional comments.

On January 5, 2017, HRSA finalized the regulations with an effective date of March 6, 2017.[52] In developing the Final Rule, HRSA considered "comments from both the NPRM and the reopening notice."[53] On August 21, 2017, HRSA requested comments on a potential additional delay until July 1, 2018.[54] HRSA received 50 comments on the proposed delay, totaling 272 pages. 20 of the comments, totaling 179 pages, were from manufacturers or groups representing manufacturers.

The Final Rule came more than six years and three months after the date of the ANPRM and Congress's deadline to promulgate CMP regulations. It is implausible to suggest that the Final Rule requires more study. Covered entities, manufacturers, and organizations representing these stakeholders have had ample opportunity to comment, and HRSA has spent years considering their input.

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[49] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210, 1,211 (Jan. 5, 2017).
[50] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation; Reopening of Comment Period, 81 Fed. Reg. 22,960 (Apr. 19, 2016).
[51] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210, 1,211 (Jan. 5, 2017).
[52] *Id.* at 1,210.
[53] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 14,332 (Mar. 20, 2017).
[54] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 39,553 (Aug., 21, 2017).

II. HRSA Considered Comments on All Key Issues

A number of the provisions in the Final Rule codified policies that have been in place for many years and are well established in the 340B program or reflect changes to the proposed rule requested by manufacturers. For example, manufacturers already must ensure that all of their covered outpatient drugs are available at 340B ceiling prices. Manufacturers also must sell at a penny those drugs in which ceiling price calculations result in a price of less than a penny. This longstanding policy is consistent with the 340B statute and treats both manufacturers and covered entities equitably. We have already noted that the CMP provisions arose from the OIG reports describing manufacturer overcharges and HRSA's lack of oversight authority.

A. HRSA Received and Considered Comments on the Ceiling Price for a New Drug

The 340B ceiling price is a key provision of the Final Rule. The 340B statute states that the 340B ceiling price is "equal to the average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] in the preceding calendar quarter, reduced by the rebate percentage," which is defined as "(i) the average total rebate required under section 1927(c) of the Social Security Act [42 U.S.C. 1396r–8(c)] with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by (ii) the average manufacturer price for such a unit of the drug during such quarter."[55]

During the first comment period, some manufacturers proposed that HRSA allow companies to estimate new drug prices by subtracting the applicable rebate percentage from the wholesale acquisition cost of the drug, and HRSA adopted this methodology in the Final Rule. In addition, HRSA considered and adopted manufacturer suggestions on the timing for calculating the actual 340B ceiling price. The proposed rule required manufacturers to estimate the 340B ceiling price for the first three quarters, to calculate the actual ceiling price beginning in the fourth quarter, and to offer refunds by the end of the fourth quarter. Some manufacturers asked that they be able to calculate actual 340B ceiling prices sooner than the fourth quarter and for more time to offer refunds to covered entities for overcharges on new drugs. HRSA responded to these concerns and changed the Final Rule to require manufacturers to calculate an actual 340B ceiling price as soon as AMP is available, which can occur as early as the second quarter, and to offer refunds within 120 days of identifying an overcharge. In the preamble to the Final Rule, HRSA acknowledged that it was responding to these commenters who had argued that a shorter estimate period was operationally feasible, would reduce administrative burdens, and would lessen the need for retroactive refunds. HRSA agreed that an AMP for a new drug may be established after one full quarter has elapsed.

[55] 42 U.S.C. § 256b(a)(1)-(2)(A). In 2011, HRSA accurately described this statutory formula as follows: 340B Ceiling Price = [(AMP) – (URA)] X Drug Package Size. HRSA, Clarification of Penny Pricing Policy, http://www.hrsa.gov/opa/programrequirements/policyreleases/pennypricingclarification112111.pdf.

B. HRSA Received and Considered Comments on Penny Pricing

The statutory formula for 340B ceiling prices can result in a price of zero, and HRSA addressed this through its penny pricing policy. If the AMP increases more quickly than the rate of inflation, § 1927(c)(2)(A) of the Social Security Act adds a supplemental rebate amount to the URA.[56] Section 1927(c)(2)(D) of the Social Security Act ensures that the URA does not exceed the AMP.[57] The URA may, however, equal the AMP, resulting in a 340B ceiling price of zero.

The statutory formula is no fluke—it reflects Congress's considered judgment that 340B prices may equal zero. Congress recently considered the Medicaid rebate at § 1927(c)(2) and expressly *endorsed* rebates that are equal to the AMP calculation. Prior to 2010, § 1927(c)(2) could result in a URA that exceeded the AMP, resulting in a *negative* price for the drug. In 2010, Congress amended § 1927(c)(2) to set a "maximum rebate amount" of 100% of AMP.[58] By this amendment, Congress plainly intended that the URA could equal AMP, which necessarily results in a 340B ceiling price of zero. In 2015, Congress extended the inflationary penalty in the Medicaid rebate provision to generic drugs, effective January 1, 2017, again confirming that the URA may equal AMP.[59] Thus, the plain language of the statutory formula can result in a ceiling price of zero, and Congress clearly intended this result.

The Final Rule adopts the statutory formula for calculating the ceiling price and clarifies details such as the unit of measure and package size to be used in the calculation. The Final Rule adds an exception to this AMP calculation consistent with HRSA's longstanding policy. When the AMP is equal to the URA, or the difference between the two figures is less than $0.01, the ceiling price will be set at $0.01 per unit.

The 340B Coalition has long supported the penny pricing policy as reasonable. The penny pricing policy relieves manufacturers from a duty to provide certain drugs at no cost while ensuring that covered entities are not charged excessively. Moreover, the statutory formula as expressed in the penny pricing policy may motivate manufacturers to stem the rate of increase of certain drug prices in order to prevent a 340B price of a penny, thus benefiting all drug purchasers nationwide.

HRSA considered several alternatives that it ultimately (and properly) rejected. These alternatives—using the federal ceiling price; a ceiling price from previous quarters in which the ceiling price was greater than zero; or nominal pricing as used in the Medicaid rebate program—could result in prices well above zero in instances where the statutory formula results in zero ceiling prices. They were plainly contrary to the statute, which contemplates ceiling prices of zero. The alternatives would have flouted the will of Congress as expressed in

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[56] 42 U.S.C. § 1396r-8(c)(2)(A).
[57] *Id.* at § 1396r-8(c)(2)(D).
[58] ACA, Pub. L. No. 111-148, § 2501, 124 Stat. 119, 309 (2010).
[59] Bipartisan Budget Act of 2015, Pub. L. No. 114-75, § 602, 129 Stat. 584, 596-597 (to be codified at 42 U.S.C. § 1396r-8(c)(3)(C)).

the statute. HRSA proposed the alternatives, permitted stakeholders to comment, considered those comments, and rightly rejected them. Nothing can be gained by reopening the rulemaking process now to rehash questions that have already been asked and answered.

C. HRSA Received and Considered Comments on CMPs

HRSA received and considered numerous comments on the CMP regulation. Covered entities urged HRSA to strengthen the provisions. Manufacturers requested more detail about the CMP regulations and suggested methods that HRSA could use to determine the amount of overcharges and which overcharges should be subject to CMPs. After this extensive and lengthy rulemaking process, HRSA finalized the CMP regulations.

The regulations should not be delayed. CMPs are needed now because they are the only viable penalty that HRSA can impose on manufacturers that violate their 340B pricing obligations. The only other potential penalty available to HRSA is to terminate a manufacturer's 340B Pharmaceutical Pricing Agreement (PPA). Terminating a manufacturer's PPA is rarely a realistic option because doing so would likely mean that Medicaid and Medicare Part B patients could no longer receive the manufacturer's drugs. This is because a manufacturer's drugs cannot be reimbursed by Medicaid and Medicare Part B unless the manufacturer has a PPA. Excluding manufacturers from the 340B program, Medicaid and Medicare Part B would clearly harm manufacturers more than assessing CMPs, which are a more modest and targeted sanction than exclusion. Moreover, covered entities rely upon HRSA to enforce manufacturers' 340B pricing obligations, as neither the 340B statute nor the PPA grants covered entities the right to enforce those obligations in a court of law.[60]

HHS's Delay of the Final Rule Is Contrary to Law

The Final Rule is long overdue. On January 5, 2017, HHS finally issued the rule, more than seven years after the CMP provision was enacted. The Final Rule was to be effective on March 6, 2017. HHS's delays to the rule on March 6, 2017 and March 20, 2017 were contrary to law because they ignored the statutory deadline set by Congress for CMP regulations, and they did not comply with APA notice-and-comment procedures. HHS should make the Final Rule effective immediately.

I. Any Delay Violates the 340B Statute and the Administrative Procedure Act

HHS's delay of the Final Rule violates the deadline for CMP regulations that Congress set in the 340B statute. In circumstances strikingly similar to HHS's delay of the CMP rule, the D.C. Circuit very recently invalidated a federal agency's unlawful attempt to delay the compliance date of a properly promulgated regulation.[61] In *Clean Air Council v. Pruitt*, the D.C. Circuit reconfirmed several bedrock principles of administrative law that prohibit HHS's proposed

[60] Astra USA, Inc. v. County of Santa Clara, 131 S. Ct. 1342 (2011).
[61] Clean Air Council v. Pruitt, 862 F.3d 1 (D.C. Cir. 2017).

delay. Any delay of a regulation's effective date is "tantamount to amending or revoking a rule."[62] To amend or revoke a rule, HHS "must comply with the Administrative Procedure Act (APA), including its requirements for notice and comment."[63] HHS's authority under the APA is not absolute, however, because "'administrative agencies may act only pursuant to authority delegated to them By Congress.'"[64] Therefore, HHS may only delay the effective date of the CMP rule if "'the new policy is permissible under the statute.'"[65]

HHS's delay in the CMP rule is plainly not permissible under the 340B statute. In clear and unambiguous language, Congress required HHS to impose "sanctions in the form of civil monetary penalties, *which shall be assessed according to standards established in regulations to be promulgated by the Secretary* ***not later than 180 days after March 23, 2010*** . . . ."[66] Congress gave HHS 180 days from March 23, 2010 to issue CMP regulations, making the deadline September 19, 2010.[67] Because HHS has missed its statutory deadline, the current delay, and any further delay, are contrary to law. HHS has no authority under the 340B statute or the APA to delay the effective date of the CMP rule.

II. HHS's Prior Delays Violate the APA

HHS's delays of the Final Rule's effective date past March 6, 2017 are contrary to the APA. Both the March 6, 2017 delay notice and the March 20, 2017 IFR were subject to APA notice-and-comment procedures because they altered the substance of the Final Rule by changing the effective date of that rule. Good cause did not exist to forgo APA procedures. The delays announced in both notices are invalid because HHS did not provide adequate notice, and HHS provided no opportunity to comment on either delay.

The APA requires an agency to publish a notice of proposed rulemaking and permit the public to comment before finalizing a substantive rule.[68] A final rule may not take effect for at least 30 days after publication.[69] These procedures apply to "amending, or repealing a rule."[70] An effective date is a substantive component of rule.[71] An agency order temporarily deferring the implementation of regulations is "the type of agency action ordinarily subject to the notice-and-comment procedure."[72] An agency may only avoid these procedures by showing "good cause."[73] An agency asserting this exception must publish with the rule the reasons for the

[62] *Id.* at 6.
[63] *Id.* at 8-9.
[64] *Id.* at 9 (quoting *Verizon v. FCC*, 740 F.3d 623, 632 (D.C. Cir. 2014).
[65] *Id.* at 14 (quoting CCC v. Fox Television Stations, Inc., 566 U.S. 502, 515 (2009).
[66] 42 U.S.C. § 256b(d)(1)(B)(vi)(I) (emphasis added).
[67] *Id.*
[68] 5 U.S.C. § 553(a)-(b).
[69] *Id.* § 553(c).
[70] 5 U.S.C. § 551(5).
[71] Nat. Res. Def. Council, Inc. v. EPA, 683 F.2d 752, 762 (3d Cir. 1982) ("NRDC I")
[72] Council of S. Mountains, Inc. v. Donovan, 653 F.2d 573, 580 (D.C. Cir. 1981).
[73] 5 U.S.C. § 553(d).

good cause exception.[74] The exception to the 30-day publication rule "'should be narrowly construed and only reluctantly countenanced.'" [75]

In *Clean Air Council*, the D.C. Circuit invalidated precisely the type of delay that HHS announced on March 6, 2017 and March 20, 2017. *Clean Air Council* concerned a final rule issued by the Environmental Protection Agency (EPA) that required certain entities to comply by June 3, 2017.[76] On April 18, 2017, EPA Administrator Scott Pruitt announced a 90-day stay of this compliance date.[77] The D.C. Circuit vacated the stay because EPA did not comply with APA notice-and-comment rulemaking requirements.[78]

HHS's delays are also strikingly similar to a delay found unlawful by the Second Circuit Court of Appeals in *Natural Resources Defense Council v. Abraham*, 355 F.3d 179 (2d Cir. 2004). In that case, the President's Chief of Staff issued a memorandum requesting that agencies postpone the effective dates of regulations that had been published in the Federal Register but had not yet become effective.[79] The Department of Energy (DOE) then published a notice in the Federal Register delaying its final rule, citing the Chief of Staff's memorandum as authority and asserting good cause for not complying with APA notice-and-comment requirements.[80] The court held that DOE's amendment to the effective date was invalid and did not alter the original effective date.[81]

Both the March 6, 2017 and March 20, 2017 notices did not actually delay the Final Rule because they did not comply with APA notice-and-comment procedures. The March 6, 2017 notice did not even claim to comply with the APA. The sole authority it cited was the January 20, 2017 memorandum from the Assistant to the President and Chief of Staff.[82] A memorandum from the Executive office of the President cannot supersede the requirements of the APA.[83]

The March 20, 2017 notice also did not delay the effective date of the Final Rule. That notice did assert good cause for circumventing APA procedures, but those claims were insufficient to overcome the statutory requirements for public participation in the rulemaking

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[74] *Id*.
[75] Nat. Res. Def. Council v. Abraham, 355 F.3d 179, 204 (2d Cir. 2004) (quoting Zhang v. Slattery, 55 F.3d 732, 744 (2d Cir. 1995)) ("NRDC II").
[76] Clean Air Council, 862 F.3d at 4.
[77] *Id.* at 5.
[78] *Id.* at 9. The D.C. Circuit also rejected the EPA's alternative arguments that the stay was authorized by the Clean Air Act. *Id.* at 8-14.
[79] NRDC II, 355 F.3d at 189-90.
[80] *Id.* at 189.
[81] *Id.* at 206.
[82] 82 Fed. Reg. at 12508-09 (citing White House Memorandum for the Heads of Executive Departments and Agencies Regarding Regulatory Freeze Pending Review (Jan. 20, 2017), https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies).
[83] NRDC II, 55 F.3d at 206.

process. In support of good cause, the notice cited, again, the January 20, 2017 memorandum from the Assistant to the President and Chief of Staff and also cited a January 20, 2017, Executive Order entitled, "Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal."[84] These Executive actions could not constitute good cause for delaying the Final Rule any more than they could justify the March 6, 2017 delay.[85]

The March 20, 2017 notice also claimed that "public health, safety, and welfare could be harmed by allowing the Final Rule to go into effect without a delay," but HRSA did not articulate any actual harm to public health, safety, and welfare that could come from the Final Rule.[86] To trigger the good cause exception, HHS must demonstrate that allowing notice-and-comment rulemaking "would do real harm."[87] Such real harm is found, for example, when an increase in helicopter crashes in Hawaii led the Federal Aviation Administration to issue emergency safety rules for air tour operators.[88] In the IFR, however, HHS did not even assert that proper rulemaking "would do real harm." Instead, HHS argued that "public health, safety, and welfare *could* be harmed," not that the public *would* be harmed, and HHS cited no actual harm that would come from the Final Rule.[89] HHS asserted a hypothetical, undefined harm, not a real harm that could constitute good cause for forgoing notice and comment.

No public harm can come from implementing regulations that either codify longstanding 340B policies or hold manufacturers accountable for violating 340B rules. Rather than discussing these unnamed harms, HHS cited vague "substantive questions raised" and unexplained "burdens raised in prior comments," particularly by manufacturers.[90] HHS opined that prior objections about the timing and "burdens" of the Final Rule "may not have been adequately considered thereby requiring additional time and public comment before the rule

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[84] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 14,332, 14,333 (Mar. 20, 2017) (citing White House Memorandum for the Heads of Executive Departments and Agencies Regarding Regulatory Freeze Pending Review (Jan. 20, 2017), https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies; White House Executive Order Minimizing the Economic Burden of PPACA Pending Repeal (Jan. 20, 2017), https://www.whitehouse.gov/the-press-office/2017/01/2/executive-order-minimizing-economic-burden-patient-protection-and). We note that, as of the date of this letter, the ACA has not been repealed, and all congressional efforts at repeal have failed. Thus, the Interim Final Rule's premise that the ACA's 340B provisions must be reviewed "pending repeal" of the ACA was mistaken. Moreover, even if this premise were not mistaken, a hypothetical future action by Congress is not good cause to forego APA rulemaking procedures when amending a properly promulgated rule.

[85] NRDC II, 55 F.3d at 206.

[86] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 14,332, 14,333 (Mar. 20, 2017).

[87] Buschmann v. Schweiker, 676 F.2d 352, 357 (9th Cir.1982) (quoting U.S. Steel Corp. v. EPA, 595 F.2d 207, 214 (5th Cir. 1979)), reh'g granted, 598 F.2d 915 (1979); see also Washington State Farm Bureau v. Marshall, 625 F.2d 296, 306-07 (9th Cir. 1980).

[88] Hawaii Helicopter Operators Ass'n v. FAA, 51 F.3d 212 (1995).

[89] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 14,332, 14,333 (Mar. 20, 2017) (emphasis added).

[90] *Id.*

goes into effect."[91] Thus, according to HHS, "[p]roviding a public comment period before delaying the effective date is impracticable given the impending deadline."

This is exactly the rationale that federal courts have rejected. The good cause exception to the APA must be narrowly construed because "circumstances justifying reliance on this exception are 'indeed rare' and will be accepted only after the court has 'examine(d) closely proffered rationales justifying the elimination of public procedures.'"[92] The "imminence of a deadline or the 'urgent need for action' is not sufficient to constitute 'good cause' within the meaning of the APA, where it would have been possible to comply with . . . the APA."[93] HRSA has now spent more than seven years studying issues surrounding the Final Rule and has gone through four rounds of public comments. The IFR admitted that HRSA considered "comments from both the NPRM and the reopening notice" when developing the Final Rule.[94] The "impending deadline" was no more than the culmination of a thorough and lengthy rulemaking process. HHS's revisiting the Final Rule was, and is, "an emergency of [HHS's] own making" that cannot constitute good cause for setting aside APA notice-and-comment procedures.[95] The exceptions to notice and comment "'are not escape clauses that may be arbitrarily utilized at the agency's whim.'"[96]

III. HHS's Delay Is Contrary to the President's Executive Order

The delay in the CMP rule does not even comply with the Assistant to the President's memorandum requesting a "Regulatory Freeze Pending Review."[97] That memorandum only requested delays where "permitted by applicable law" and directs that agencies "[e]xclude from the actions requested" in the memorandum "any regulations subject to statutory or judicial deadlines."[98] The CMP regulation is subject to a long-passed statutory deadline and should be implemented now. HHS has missed that deadline by seven years, and covered entities are still waiting for HRSA to have the enforcement tools it needs to adequately ensure that manufacturers comply with their 340B pricing obligations.

Any Additional Rulemaking Should Supplement, Rather Than Modify, the Final Rule

HHS said it proposed "to further delay the effective date of the ... final rule because it continues to examine important substantive issues in matters covered by the rule [and] intends

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[91] *Id.*
[92] Council of S. Mountains, Inc., 653 F.2d at 580.
[93] NRDC I, 683 F.2d at 765.
[94] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 14,332 (Mar. 20, 2017)
[95] NRDC II, 355 F.3d at 205.
[96] *Id.* (quoting Envtl. Defense Fund, Inc. v. EPA, 716 F.2d 915, 920 (D.C. Cir. 1983).
[97] White House Memorandum for the Heads of Executive Departments and Agencies Regarding Regulatory Freeze Pending Review (Jan. 20, 2017), https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies).
[98] *Id.*

to engage in additional rulemaking on these issues." The meaning of "additional rulemaking" is unclear because HHS did not elaborate on its intent or specify which issues more rulemaking would address. If HHS decides to proceed with additional rulemaking, we ask that the rulemaking supplement, rather than modify, the final rule, as there have already been four rounds of comments that have allowed HRSA to carefully and thoroughly consider stakeholder input on issues addressed in the final rule.

Conclusion

We believe that the Final Rule is crucial to codify important 340B policies and to ensure that manufacturers comply with 340B program requirements. We urge HHS to implement the Final Rule immediately. We thank HHS for the opportunity to comment on the proposed delay. If you have any questions or need additional information, please do not hesitate to reach out to any of the individuals in the attached list of organizational contacts.

Sincerely,

The 340B Coalition
Ryan White Clinics for 340B Access

Organizational Contacts

Colleen Meiman
Director of Regulatory Affairs
National Association of Community Health Centers
202-296-0158; cmeiman@ncachc.org

Joe Pugliese
President
The Hemophilia Alliance
215-439-7173; joe@hemoalliance.org

Mindy McGrath
Director of Advocacy & Communications
National Family Planning & Reproductive Health Association
202-552-0114 ext. 206; mmcgrath@nfprha.org

Britten Pund
Director, Health Care Access
National Alliance of State & Territorial AIDS Directors
202-434-8044; bpund@nastad.org

Stephanie Arnold Pang
Director of Policy and Communications
National Coalition of STD Directors
202-842-4660; sarnold@ncsddc.org

Brian Bowden
Associate Legislative Director, Health
National Association of Counties
202-942-4275; bbowden@naco.org

Amanda Cook
Manager, Federal Affairs
Children's Hospital Association
202-753-5328; amanda.cook@childrenshospitals.org

Beth Feldpush
Senior Vice President, Policy and Advocacy
America's Essential Hospitals
202-585-0111; bfeldpush@essentialhospitals.org

Greg Doggett
Legal and Policy Counsel
340B Health
202-552-5859; greg.doggett@340bhealth.org

Sara Dingwall
President
Ryan White Clinics for 340B Access
772-468-9900; sdingwall@wholefamilyhealthcenter.org

Medicaid Rebate Settlements with 340B Repayments

Below is a chart of settlements that the federal government entered into with various pharmaceutical manufacturers over the past nearly 15 years based on allegations that the companies overcharged Medicaid by misreporting Medicaid "best price." Based on a review of publicly available information about the settlements, it appears that the settlements included a requirement that the manufacturer repay covered entities participating in the 340B drug pricing program. The statutory formulas for calculating Medicaid rebates and 340B discounts are virtually identical. When manufacturers underpay Medicaid rebates by overstating a drug's best price, it necessarily follows that they have overcharged covered entities by overstating the 340B ceiling price.

Manufacturer Name	Drug(s) Involved	Period/Quarters Covered by Settlement	Settlement Date	Settlement Amount
Mylan Inc.	EpiPen	July 29, 2010 – Mar. 31, 2017	Aug. 2017	$465 million, including $19.3 million to 340B covered entities
GlaxoSmithKline	Multiple drugs (not specified in relevant section of DOJ press release)	1994-2003	July 2, 2012	$3 billion, including $20.2 million to 340B covered entities
Dava Pharmaceuticals	cefdinir, clarithromycin, methotrexate, and rheumatrex	Oct. 1, 2005 – Sep. 30, 2009	Feb. 8, 2012	$11 million, including $200,000 to 340B covered entities
Mylan Pharmaceuticals Inc. and UDL Laboratories Inc.	Various	2000-2004	Oct. 19, 2009	$118 million, including $7.3 million to 340B covered entities
Aventis Pharmaceuticals	Azmacort, Nasacort, and Nasacort AQ	Oct. 1, 1995 – Sep. 30, 2000	May 28, 2009	$95.5 million, including $6.5 million to 340B covered entities
Eli Lilly	Zyprexa	Sep. 1999 – Mar. 2001	Jan. 2009	$1.43 billion, including more than $75,000 to 340B covered entities

Cephalon Inc.	Gabitril, Actiq, and Provigil	Jan. 2001 through at least 2006	Oct. 2008	$425 million, including at least $1.8 million to 340B covered entities
Merck	Zocor, Vioxx	April 1998 – Mar. 2006	Feb. 7, 2008	$671 million, including $9 million to 340B covered entities
Bristol-Myers Squibb	Serzone	1st Qtr. '97 – 4th Qtr. '97	Sep. 28, 2007	$515 million, including $124,000 to 340B covered entities
Schering-Plough	Claritin Redi-Tabs and K-DUR	Redi-Tabs: 4th Qtr. '98 – 2nd Qtr. '02	Aug. 29, 2006	$255 million civil settlement ($180 million in criminal fines), including at least $3.9 million to 340B covered entities
		K-DUR: 2nd Qtr. '96 – 2nd Qtr. '01		
KING Pharmaceuticals	Entire Drug Line	Jan. 1994 – Dec. 31, 2002	Oct. 31, 2005	$124 million, including at least $7 million to 340B covered entities
Schering-Plough	Claritin	Jan. 1998 – Dec. 31, 2002	July 2004	$345 million, including at least $10.6 million to 340B covered entities
Bayer and GSK	Cipro, Adalat CC, Flonase and Paxil	Cipro: 1st Qtr. '96 – 1st Qtr. '01	April 2003	Bayer: $257 million, including at least $2.5 million to 340B covered entities
		Adalat CC: 4th Qtr. '97 – 1st Qtr. '00		
		Flonase: 3rd Qtr. '97 – 3rd Qtr. '00		GSK: $87.6 million, including

		Paxil: 1st Qtr. '01		at least $9.4 million to 340B covered entities