

THE 340B COALITION

April 19, 2017

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

Re: RIN 0906-AA89 - Comments on Interim Final Rule Delaying 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 Interim Final Rule published in the Federal Register on March 20, 2017 (IFR).¹ The IFR delays 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 IFR delayed this effective date to May 22, 2017 with a possible further delay to October 1, 2017. The 340B Coalition strongly opposes both delays because they will harm 340B covered entities and the patients that they serve, and because the delays are contrary to both the Administrative Procedure Act (APA) and the 340B statute. The 340B Coalition urges the Health Resources and Services Administration (HRSA) 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.

Background

Manufacturer overcharges have long plagued the 340B program. The Department of Health and Human Services (HHS) Office of the Inspector General (OIG) issued two reports in

¹ *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 82 Fed. Reg. 14,332 (Mar. 20, 2017) (RIN 0906-AA89) (IFR).

² *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 82 Fed. Reg. 1,210 (Jan. 5, 2017) (Final Rule).

the mid-2000s detailing this problem. On March 10, 2003, the OIG issued a report titled “Pharmaceutical Manufacturers Overcharged 340B-Covered Entities.”³ In October 2005, the OIG issued a second report titled “Deficiencies in the Oversight of the 340B Drug Pricing Program.”⁴

The 2003 OIG report reviewed sales of eleven prescription drugs by five manufacturers during the one-year period ending September 1, 1999 to determine whether the manufacturers overcharged 340B covered entities.⁵ The OIG determined that the five manufacturers overcharged 340B covered entities for all eleven drugs.⁶ The OIG estimated that the manufacturers overcharged covered entities \$6.1 million during the one-year period ending September 30, 1999 and that these overcharges represented 45% of the amount paid by covered entities.⁷

The 2005 OIG report focused on HRSA’s administration and oversight of the 340B program, and the OIG made 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.⁸ The OIG found that HRSA lacked the oversight mechanisms and authority to ensure that 340B entities pay at or below the 340B ceiling price.⁹ Participating entities could not independently verify that they receive the correct 340B discount.¹⁰

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.¹¹ 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.¹² The OIG also recommended that HRSA institute oversight mechanisms to validate its 340B price calculations and the prices charged to participating entities. These mechanisms included auditing manufacturers, wholesalers and covered entities.¹³ The OIG viewed HRSA’s limited options for enforcing manufacturer compliance as

³ Dep’t of HHS OIG, *Pharmaceutical Manufacturers Overcharged 340B-Covered Entities*, A-06-01-00060, OIG (Mar. 10, 2003), <https://oig.hhs.gov/oas/reports/region6/60100060.pdf>.

⁴ Dep’t of HHS OIG, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-0072, OIG (Oct. 2005), <https://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf>.

⁵ Dep’t of HHS OIG, *Pharmaceutical Manufacturers Overcharged 340B-Covered Entities*, A-06-01-00060, at 3.

⁶ *Id.*

⁷ *Id.*

⁸ Dep’t of HHS OIG, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-0072, at ii, 10-11.

⁹ *Id.* at ii-iii, 15-17.

¹⁰ *Id.* at iii, 18.

¹¹ *Id.* at iii, 21.

¹² *Id.* at iii, 21.

¹³ *Id.* at iii-iv, 21-22.

significant shortcomings in the 340B program. Thus, the OIG recommended that HRSA seek authority to establish penalties for 340B violations.¹⁴

In response to these OIG reports, the House Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce held a hearing on oversight and administration of the 340B program.¹⁵ 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.”¹⁶ 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.”¹⁷

Congress responded in 2010 by enacting several important revisions to the 340B statute.¹⁸ As amended, the statute requires the Secretary of HHS to implement certain “improvements in program integrity” for the 340B program.¹⁹ 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, 2010.²⁰ 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.”²¹ 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.²² The public comment period for the June 17, 2015 proposed rule closed on August 17, 2015, and HRSA received 35 comments.²³ On April 19, 2016, HRSA reopened comments on the proposed rule and sought additional comments on three areas: 1) HRSA’s “penny price” policy for ceiling

¹⁴ *Id.* at iv, 22.

¹⁵ *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).

¹⁶ *Id.* at 20.

¹⁷ *Id.*

¹⁸ 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)).

¹⁹ 42 U.S.C. § 256b(d).

²⁰ *Id.* § 256b(d)(1)(B)(vi)(I).

²¹ *340B Drug Pricing Program Manufacturer Civil Monetary Penalties*, 75 Fed. Reg. 57,230 (Sept. 20, 2010) (“ANPRM”).

²² *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 80 Fed. Reg. 34,583 (June 17, 2015) (“Proposed Rule”).

²³ *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 82 Fed. Reg. 1,210, 1,211 (Jan. 5, 2017) (“Final Rule”).

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.²⁴ This second comment period closed on May 19, 2016, and HHS received 70 comments.²⁵ On January 5, 2017, HRSA finalized the regulations with an effective date of March 6, 2017.²⁶ 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.”²⁷ 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.²⁸ 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.”²⁹ 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.”³⁰

In response to the Assistant Director’s memorandum, HRSA published a “Final rule; correcting Amendment” on March 6, 2016 that delayed the Final Rule until March 21, 2017.³¹

²⁴ *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation; Reopening of Comment Period*, 81 Fed. Reg. 22,960 (Apr. 19, 2016) (“*Reopened Rule*”).

²⁵ *Final Rule*, 82 Fed. Reg. at 1,211

²⁶ *Id.* at 1,201.

²⁷ <https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies>.

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties; Delay of Effective Date*, 82 Fed. Reg. 12,508 (Mar. 6, 2017) (“*340B CMP Rule Delay*”). .

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On March 20, 2017, HRSA issued the IFR further delaying the Final Rule until May 22, 2016 and requesting comments on a possible additional delay until October 1, 2017.³²

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 the 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.³³ Substantial drug price increases negatively impact providers' financial health and, in turn, their ability to care for patients.³⁴ Therefore, it is critically important that HRSA have the tools it needs to ensure that covered entities are not subjected to overcharges by manufacturers.

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."³⁵ National hospital data show the importance of 340B savings to hospitals that participate in the program. 340B Disproportionate share (DSH) hospitals provide significantly more care to Medicaid and low-income Medicare patients than non-340B hospitals.³⁶ Although 340B DSH hospitals account for only 36% of all Medicare acute care hospitals, they provide nearly 60% of all uncompensated care.³⁷ DSH hospitals in the 340B program are also significantly more likely than non-340B hospitals to offer vital health care services that are often unreimbursed, which

³² IFR, 82 Fed. Reg. 14,332.

³³ U.S. Department of Health & Human Services, 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>.

³⁴ 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>.

³⁵ H.R. Rep. 102-384, 102d Cong., pt.2, at 12 (2d Sess. 1992).

³⁶ 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.

³⁷ *Id.*

include trauma centers, HIV/AIDS services, and immunizations.³⁸ Compared to non-340B providers, 340B DSH hospitals treat many more Medicare Part B patients who are dually eligible for Medicaid, disabled, have end stage renal disease or are members of racial or ethnic minorities.³⁹ 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.⁴⁰

Many covered entities rely on their 340B program savings to meet the needs of their low-income, rural or otherwise vulnerable 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 wellbeing. 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 supports 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 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 2020⁴¹ 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-

³⁸ *Id.*

³⁹ 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.

⁴⁰ NC Rural Health Research Program, *80 Rural Hospital Closures: January 2010 – Present*, <http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/>.

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.

We know of Federally Qualified Health Centers (FQHCs) that use the savings from the 340B program to provide free or heavily discounted medications to indigent, underinsured or uninsured patients. Savings from the 340B program support otherwise unfunded dietitian services, smoking cessation services, education services, social services and community outreach in these FQHCs.

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 has been recognized both by Congress and HHS. The CMP provision grew from congressional hearings in 2005 in response to OIG reports documenting manufacturer overcharges and HRSA's inability to impose sanctions. That report, *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."⁴²

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 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.⁴³

Since 2010, Congress has granted HRSA CMP authority to provide it with the necessary oversight. HRSA 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. Covered entities cannot fulfill their vital missions to help America's low-income, uninsured and underinsured patients if manufacturers overcharge covered entities for

⁴² Dep't of 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>.

⁴³ *Astra USA, Inc. v. Santa Clara County, Cal.*, 563 U.S. 110, 121-22 (2011).

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.⁴⁴ HRSA then spent almost five years considering that input and finally issued a notice of proposed rulemaking in June 2015.⁴⁵ HRSA received 35 comments totaling 283 pages.⁴⁶ Several organizations in the 340B 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 comment letters 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.⁴⁷ This second comment period closed on May 19, 2016, and HHS received 70 comments.⁴⁸ This second round of comments totaled 385 pages. 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 Squibb and Recordati

⁴⁴ ANPRM, 75 Fed. Reg. 57,230.

⁴⁵ Proposed Rule, 80 Fed. Reg. 34,583.

⁴⁶ Final Rule, 82 Fed. Reg. at 1,211.

⁴⁷ 340B CMP Reopened Rule, 81 Fed. Reg. 22,960.

⁴⁸ 340B CMP Final Rule, 82 Fed. Reg. at 1,211

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, 2017.⁴⁹ In developing the Final Rule, HRSA considered “comments from both the NPRM and the reopening notice.”⁵⁰ The January 5, 2017 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.

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’s 2003 and 2005 reports describing manufacturer overcharges and HRSA’s lack of oversight authority.

A. HRSA Received and Considered Comments on the Ceiling Price

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.”⁵¹

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

⁴⁹ *Id.* at 1,201.

⁵⁰ *IFR*, 82 Fed. Reg. at 14,332.

⁵¹ 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>.

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.

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.⁵² Section 1927(c)(2)(D) of the Social Security Act ensures that the URA does not exceed the AMP.⁵³ 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.⁵⁴ 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.⁵⁵ 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.

⁵² 42 U.S.C. § 1396r-8(c)(2)(A).

⁵³ *Id.* § 1396r-8(c)(2)(D).

⁵⁴ ACA, Pub. L. No. 111-148, § 2501, 124 Stat. 119, 309 (2010).

⁵⁵ 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 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 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 the CMP Regulation

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.⁵⁶

Any Further Delay of the Final Rule Is Contrary to Law

The Final Rule is long overdue. On January 5, 2017, HRSA finally issued the rule, more than seven years after the CMP provision was enacted. The Final Rule was to be effective on

⁵⁶ *Astra USA, Inc. v. County of Santa Clara*, 131 S. Ct. 1342 (2011).

March 6, 2017. HHS's delays to the rule on March 6, 2017 and March 20, 2017 are contrary to law because they did not comply with APA notice-and-comment procedures, and they ignore the statutory deadline set by Congress for CMP regulations. HRSA should make the Final Rule effective immediately.

I. Further 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 are subject to APA notice-and-comment procedures because they altered the substance of the Final Rule by changing the effective date of that rule. 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. Good cause did not exist to forgo APA procedures.

The APA requires an agency to publish a notice of proposed rulemaking and permit the public to comment before finalizing a substantive rule.⁵⁷ A final rule may not take effect for at least 30 days after publication.⁵⁸ These procedures apply to "amending, or repealing a rule."⁵⁹ An effective date is a substantive component of rule.⁶⁰ An agency order temporarily deferring the implementation of regulations is "the type of agency action ordinarily subject to the notice-and-comment procedure."⁶¹ An agency may only avoid these procedures by showing "good cause."⁶² An agency asserting this exception must publish with the rule the reasons for the good cause exception.⁶³ The exception to the 30-day publication rule "'should be narrowly construed and only reluctantly countenanced.'" ⁶⁴

HHS's delays are 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.⁶⁵ 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.⁶⁶ The

⁵⁷ 5 U.S.C. § 553(a)-(b).

⁵⁸ *Id.* § 553(c).

⁵⁹ 5 U.S.C. § 551(5).

⁶⁰ *Nat. Res. Def. Council, Inc. v. EPA*, 683 F.2d 752, 762 (3d Cir. 1982) ("*NRDC I*").

⁶¹ *Council of S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 580 (D.C. Cir. 1981).

⁶² 5 U.S.C. § 553(d).

⁶³ *Id.*

⁶⁴ *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*").

⁶⁵ *Id.* at 189-90.

⁶⁶ *Id.* at 189.

court held that DOE's amendment to the effective date was invalid and did not alter the original effective date.⁶⁷

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.⁶⁸ A memorandum from the Executive Office of the President cannot supersede the requirements of the APA.⁶⁹

The March 20, 2017 notice also does 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 process. In support of good cause, the notice cites, again, the January 20, 2017 memorandum from the Assistant to the President and Chief of Staff and also cites a January 20, 2017, Executive Order entitled, "Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal."⁷⁰ These Executive actions cannot constitute good cause for delaying the Final Rule any more than they could justify the March 6, 2017 delay.⁷¹

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 HHS did not articulate any actual harm to public health, safety, and welfare that could come from the Final Rule.⁷² To trigger the good cause exception, HHS must demonstrate that allowing notice-and-comment rulemaking "would do real harm."⁷³ Such real harm is found, for example, when an increase in

⁶⁷ *Id.* at 206.

⁶⁸ 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>).

⁶⁹ *NRDC II*, 55 F.3d at 206.

⁷⁰ *IFR*, 82 Fed. Reg. at 14,333 (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/2017/01/20/executive-order-minimizing-economic-burden-patient-protection-and>). We note that as of the date of this letter, the ACA has not been repealed. Moreover, the 340B provisions of the ACA were not included in the American Health Care Act of 2017 (AHCA), HR 1628, which would have repealed much of the rest of the ACA. The AHCA was introduced in the House on March 20, 2017 but has not been put to a vote due to an apparent lack of majority support. No comparable bill is pending in the Senate. Thus, the IFR'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.

⁷¹ *NRDC II*, 55 F.3d at 206.

⁷² *IFR*, 82 Fed. Reg. at 14,333.

⁷³ *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).

helicopter crashes in Hawaii led the Federal Aviation Administration to issue emergency safety rules for air tour operators.⁷⁴ In the IFR, however, HHS does not even assert that proper rulemaking “would do real harm.” Instead, HHS argues 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.⁷⁵ 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.⁷⁶ 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 goes into effect.”⁷⁷ 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.’”⁷⁸ 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.”⁷⁹ HRSA has spent approximately seven years studying issues surrounding the Final Rule and has gone through three rounds of public comments. The IFR admits that HRSA considered “comments from both the NPRM and the reopening notice” when developing the Final Rule.⁸⁰ The “impending deadline” is no more than the culmination of a thorough and lengthy rulemaking process. HHS’s desire now to revisit the Final Rule is “an emergency of [HHS’s] own making” that cannot constitute good cause for setting aside APA notice-and-comment procedures.⁸¹ The exceptions to notice and comment “are not escape clauses that may be arbitrarily utilized at the agency’s whim.”⁸²

⁷⁴ *Hawaii Helicopter Operators Ass’n v. FAA*, 51 F.3d 212 (1995).

⁷⁵ *IFR*, 82 Fed. Reg. at 14,333 (emphasis added).

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Council of S. Mountains, Inc.*, 653 F.2d at 580.

⁷⁹ *NRDC I*, 683 F.2d at 765.

⁸⁰ *IFR*, 82 Fed. Reg. at 14,332.

⁸¹ *NRDC II*, 355 F.3d at 205.

⁸² *Id.* (quoting; *Env’tl. Defense Fund, Inc. v. EPA*, 716 F.2d 915, 920 (D.C. Cir. 1983)).

II. Further Delays Violate the 340B Statute

Any further delay in the Final Rule will also violate the deadline for CMP regulations that Congress set in the 340B statute. Congress gave HHS 180 days from March 23, 2010 to issue CMP regulations, making the deadline September 19, 2010.⁸³ Because HHS has missed its statutory deadline, the current delay and any further delay are contrary to law. For the same reason, the delays do not even comply with the Assistant to the President's memorandum requesting a "Regulatory Freeze Pending Review."⁸⁴ That memorandum only requests 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."⁸⁵ The CMP regulation is subject to a long passed statutory deadline and should be implemented now. HHS has missed that deadline by more than six years, and covered entities are still waiting for HHS to have the enforcement tools it needs to adequately ensure that manufacturers are complying with their 340B pricing obligations.

Conclusion

The 340B Coalition believes that the Final Rule is crucial to codify important 340B policies and to ensure that manufacturers comply with 340B program requirements. We urge HRSA to make the Final Rule effective immediately. The 340B Coalition thanks HRSA for the opportunity to comment on the IFR. 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

⁸³ 42 U.S.C. § 256b(d)(1)(B)(vi)(I).

⁸⁴ <https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies>.

⁸⁵ *Id.*

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