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**BEFORE THE U.S. SENATE HEALTH, EDUCATION, LABOR AND PENSIONS
COMMITTEE**

PERSPECTIVES ON THE 340B DRUG DISCOUNT PROGRAM

March 15, 2018

Chairman Alexander, Ranking Member Murray and members of the Committee, thank you for inviting me to participate in today's hearing and thank you for devoting a full committee hearing to the 340B program, which is an important topic that deserves attention from everyone concerned about rising health care costs.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. The biopharmaceutical sector is one of the most research-intensive industries in the United States: Since 2000, PhRMA member companies have invested more than half a trillion dollars in the search for new treatments and cures, including \$65.5 billion in 2016 alone.

The 340B Program Plays a Critical Role in America's Safety Net

PhRMA and our member companies strongly support the 340B program and the important role it plays in our health care safety-net. The 340B program is particularly crucial to supporting the care provided by recipients of Health Resources and Services Administration (HRSA) grants (known as "grantees"). Grantees—including Community Health Centers, Ryan White clinics and hemophilia treatment centers—serve our nation's most vulnerable patients, many of whom are often without other sources of care. These grantees are on the front lines of public health threats and represent a lifeline for many vulnerable patients—treating serious conditions like HIV, hemophilia and hepatitis C or providing lifesaving cancer screenings and other health services. The 340B program needs to be modified so that it is on a sustainable path and can continue to support grantees and other true safety-net providers. Any changes must seek to eliminate the growing abuses of recent years that distort markets and increase health costs without contributing to its safety-net mission.

I'm pleased to be testifying today with Carolina Health Centers, a community health center grantee. Community Health Centers (CHCs) serve as the primary medical home for more than 27

million people in 10,400 rural and urban communities across America.¹ The 340B discounts our member companies and other biopharmaceutical manufacturers provide to these health centers help CHCs deliver free and reduced cost medicines and other services to their patients. Consistent with the purpose of the 340B program, CHCs and other grantees typically serve a population heavily skewed to low-income or vulnerable patients.

We also want to recognize the important public health role of our nation's public hospitals. Public hospitals play a crucial role as a source of care for those with nowhere else to turn. Often these are the hospitals providing high levels of charity care to low-income patients. Analysis of Medicare data shows that 24 percent of 340B disproportionate share hospitals (DSH) provide 80 percent of the charity care provided by all 340B DSH hospitals. That same small percentage of 340B DSH hospitals represent only 50 percent of total patient costs and 45 percent of total hospital beds in all 340B facilities, meaning that they are providing a disproportionately high level of charity care relative to their size.² Many of the hospitals that are shouldering this disproportionate burden are public hospitals. The 340B program was designed to help support this type of care.

When Congress created the 340B program a quarter of a century ago,³ it was intended to assist federal grantees, like CHCs, and true safety-net hospitals serving large numbers of uninsured or otherwise vulnerable patients. Under the terms of the program, hospitals and safety-net clinics that meet certain eligibility criteria are entitled to discounts that average about 50 percent of the cost of outpatient prescription medicines.⁴ As a condition of participating in Medicaid, biopharmaceutical companies must also participate in the 340B program.⁵

A key distinction between grantees and hospitals is in their reporting requirements. Safety-net clinics must generally meet federal requirements of reinvesting their revenue into care for uninsured or vulnerable patients as part of their grant requirements. In contrast, current 340B program rules lack any standards for how 340B discounts should be used by 340B hospitals or even how much hospitals can reap in profits by marking up prices charged to patients and payers when administering them medicines acquired at the discounted 340B price mandated by law (see Figure 1).

The lack of program standards for use of 340B discounts by DSH hospitals, combined with the significant growth of the program driven by these hospitals, has greatly

¹ National Association of Community Health Centers, "About Our Health Centers," Available at: <http://www.nachc.org/about-our-health-centers/> (accessed March 11, 2018).

² Alliance for Integrity and Reform of 340B, "Benefiting Hospitals, Not Patients: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program," Spring 2016.

³ Public Law 102-585, Veterans Health Care Act of 1992

⁴ Congressional Budget Office, "Prices for Brand-Name Drugs Under Selected Federal Programs," June 2005.

⁵ 42 U.S.C. § 1396r-8(a)(1), (a)(5).

transformed the 340B program. It is no longer accurate to characterize the program as primarily focused on care for vulnerable patients by safety-net providers. Instead, 80 percent of the sales are to DSH hospitals and their child sites, more than two thirds of which provide below average levels of free and reduced cost treatments to uninsured or vulnerable patients.⁶ As a 2014 *Health Affairs* study on 340B put it, the program has evolved “from [a program] that serves vulnerable communities to one that enriches hospitals.”⁷

Figure 1:



While grantees like CHCs rely on the 340B program to help them provide care to underserved or vulnerable populations, growing DSH hospital abuse of 340B drives up health care costs for others in the health care system. Economists publishing in *The New England Journal of Medicine*⁸ and *JAMA*,⁹ along with the Government Accountability Office (GAO),¹⁰ have concluded that 340B creates hospital incentives that increase costs for patients, insurers and the government, while reducing the viability of community-based physicians. For example, recent evidence points to the role of 340B in hospitals buying up community-based physicians in

⁶ Alliance for Integrity and Reform of 340B, “Benefiting Hospitals, Not Patients: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program,” Spring 2016.

⁷ R. Conti, P. Bach. “The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities,” *Health Affairs* 33, no. 10 (2014): 1786-1792.

⁸ S. Desai and J.M. McWilliams, “Consequences of the 340B Drug Pricing Program,” *N Engl J Med* 2018.

⁹ R. Conti, P. Bach, “Cost Consequences of the 340B Drug Discount Program,” *JAMA: The Journal of the American Medical Association*, 2013;309(19):1995-1996. doi:10.1001/jama.2013.4156.

¹⁰ Government Accountability Office, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, GAO-15-442, June 2015.

wealthy areas¹¹ and shifting care to the hospital outpatient setting where it is often more expensive.¹² At the same time, hospitals are also able to sharply markup the price of medicines accessed through 340B when treating privately insured patients at acquired clinics, with no obligation to reinvest those resources in safety-net services. In fact, a recent *New England Journal of Medicine* study reports DSH hospital eligibility was associated with lower proportions of low-income patients treated for the conditions studied and “no significant differences in hospital provision of safety-net or inpatient care for low-income groups...”¹³ In sharp contrast, evidence shows CHCs and other grantees are using the 340B program as intended due to the requirements of their HRSA grants.

There is a clear need for improvements to the 340B program to avoid abuses while sustaining its focus on strengthening the safety net. Improvements must reflect the critical role of grantees, who need continued access to the program without being burdened by new restrictions. At the same time, there is an urgent need to modernize the program to assure that patients benefit and to reduce the unintended distortion of markets and promotion of higher costs in the health care system that have emerged as the program has strayed from its intent.

Today’s 340B Program is Nearly Unrecognizable from the Program Congress Enacted in 1992; Changes Have Contributed to the Many Problems Now Associated with the Program

Congress enacted the 340B drug pricing program in 1992, as part of the Veterans’ Health Care Act,¹⁴ in part to address the unintended consequences of the Medicaid rebate statute enacted in the Omnibus Budget Reconciliation Act (OBRA) of 1990.

As enacted in 1990, the Medicaid rebate statute required biopharmaceutical manufacturers to provide Medicaid with steep rebates to give state Medicaid programs the “best price” among most purchasers. Consequently, sales to clinics and hospitals previously receiving generous voluntary manufacturer discounts were suddenly required under the Medicaid rebate law to be included in manufacturer rebate calculations and potentially setting a new Medicaid “best price” that had to be offered to the entire Medicaid program. As described in the House Energy and Commerce Committee’s 1992 report, the “best price” provision created a disincentive for manufacturers to offer lower prices to safety-net facilities, because that price could trigger higher Medicaid rebates nationwide. The report cites testimony and other information indicating loss of

¹¹ R Conti and P Bach, “The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities,” *Health Affairs*, Vol. 33, No. 10, October 2014; Avalere Health, “Hospital Acquisitions of Physician Practices and the 340B Program,” June 2015, available at: <http://avalere.com/expertise/life-sciences/insights/avalere-white-paper-hospital-acquisitions-of-physician-practices-and-the-34> (accessed March 11, 2018).

¹² P. Bach and R.H. Jain, “Physician’s Office and Hospital Outpatient Setting in Oncology: It’s About Prices, Not Use,” *Journal of Oncology Practice* 2017 13:1, 4-5.”; IMS Institute for Healthcare Informatics. *Global Oncology Trend Report: A Review of 2015 and Outlook to 2020*, June 2016.

¹³ S. Desai and J.M. McWilliams, “Consequences of the 340B Drug Pricing Program,” *N Engl J Med* 2018.

¹⁴ Public Law 102-585, Veterans Health Care Act of 1992

manufacturer discounts or special pricing practices at federally-funded clinics and public hospitals after OBRA 1990.¹⁵

As a result, the 340B drug pricing program arose because of the Medicaid statute's unanticipated impact on safety-net facilities and helped ensure discounted medicines for specified covered entities.

Original intent of the program

Congress did not create the 340B program to benefit a random assortment of hospitals that might or might not serve as a safety net for low-income uninsured patients. Nor does it appear that Congress sees the program's purpose that way today. Some have suggested the 340B program was intended to benefit hospitals, with no regard for patients. In fact, the statute and its legislative history reflect an express congressional intent to create a program with a very important and targeted purpose. Meanwhile, the silence in the 340B legislative history about practices that have become common in the program today is noteworthy:

- There are no indications that 340B was expected to become a program dominated by DSH hospitals rather than focused on federal grantees who operate in an entirely different manner, generally using 340B to provide care to uninsured or vulnerable patients as part of their grant requirements.
- There are no statements that the 340B program was designed to be a new and unaccountable revenue stream funding any spending a hospital selects.
- There is no indication that hospitals were expected to charge patients and their insurers markups equal to 200 percent or more above a medicine's discounted 340B acquisition price, or often fail to provide discounts to the people who need them.
- There is no suggestion that the program would grow to include hospital outpatient facilities in affluent communities or cover more than 60 percent of total Part B hospital drug purchases.¹⁶
- There is no suggestion that 340B was intended to drive utilization patterns and health system consolidation that increases the cost of health care for all patients and insurers.

PhRMA believes that the large discounts biopharmaceutical manufacturers provide under the 340B program should serve a targeted purpose—helping low-income uninsured and other vulnerable patients obtain the outpatient medicines they need—and true safety-net hospitals qualifying for the program should be accountable for using its benefits properly.

Medicaid expansion and growth in coverage for medicines has changed the environment

¹⁵ H.R. Rep. 102-384, Pt. 2 (1992), pp. 9-11.

¹⁶ Alliance for Integrity and Reform of 340B, "340B Hospitals Vs. Non-340b Hospitals: Growth and Distribution of Physician-Administered Drug Reimbursement Across Ten Therapeutic Areas," Feb 2016, available at: <http://340breform.org/userfiles/02.02.16%20BRG%20340B%20Part%20B%20Fact%20Sheet.pdf> (accessed March 13, 2018).

Dramatic changes in health coverage in the quarter of a century since 340B was created mean the program is operating in a very different environment today. Some of these changes have contributed to the rampant growth in the program and raise questions about how the program is being used today. For example, Medicaid enrollment has increased from 29 million individuals in 1992 to more than 72 million individuals in 2016,¹⁷ and the share of the U.S. population on Medicaid has increased from 11 percent to 22 percent over that same period.¹⁸ This has contributed to a sharp increase in the number of hospitals eligible to participate in the 340B program because of the use of the DSH metric to determine DSH hospital eligibility for the program. While 340B is an outpatient-only program, the DSH metric looks at inpatient care. Consequently, more and more hospitals now qualify for 340B discounts as the proportion of inpatient stays covered by Medicaid increases. There is no indication in the legislative history of 340B that this significant expansion in Medicaid eligibility and enrollment and the resulting impact on 340B's size and character were foreseen when the program was created. Nor is there any indication in the 340B law's legislative history that Congress focused on the fact that the DSH metric would expand hospital 340B eligibility if individuals shifted from being uninsured to being covered through Medicaid, an anomalous result of the current formula.

Insurance coverage for prescription medicines has also changed dramatically in the last couple decades. In 1992, 57 percent of prescription medicine costs were paid out of pocket by patients, making it crucial that biopharmaceutical manufacturers could provide free and discounted medicines to safety-net facilities so that patients who could not afford the out-of-pocket costs could still obtain access to needed medicines.¹⁹ By 2016, 14 percent of costs were paid out of pocket by patients,²⁰ in part due to Medicare patients benefiting from the Part D program and medicines being recognized as integral to good health care. Even as coverage of medicines expanded, the 340B program has grown dramatically—sharply outpacing overall prescription drug sales.²¹ This growth has been fueled by DSH hospitals' use of the 340B program,²² including their ability to take advantage of increased prescription medicine coverage through markups on 340B medicines used by insured patients.

¹⁷ MACStats: Medicaid and CHOP-Data Book, "Section 2, Exhibit 10: Medicaid Enrollment and Total Spending Levels and Annual Growth, FYs 1966-2016," December 2017. Available at: <https://www.macpac.gov/wp-content/uploads/2015/11/EXHIBIT-10.-Medicaid-Enrollment-and-Total-Spending-Levels-and-Annual-Growth-FYs-1966%E2%80%932016.pdf>

¹⁸ Analysis of MACStats: Medicaid and CHOP-Data Book, "Section 2, Exhibit 10: Medicaid Enrollment and Total Spending Levels and Annual Growth, FYs 1966-2016," December 2017 and Census Bureau Population estimates, July 1992 and 2016.

¹⁹ Analysis of National Health Expenditure Accounts data.

²⁰ Analysis of National Health Expenditure Accounts data.

²¹ A. Vandervelde and E. Blalock, "Measuring the Relative Size of the 340B Program: 2012-2017," Berkeley Research Group, July 2017.

²² Aaron Vandervelde and Eleanor Blalock, "340B Program Sales Forecast: 2016 – 2021," 2016, available at: <http://340breform.org/userfiles/December%202016%20BRG%20Growth%20Study.pdf> (accessed March 11, 2018).

HRSA's choices in administering the program have fueled dramatic program growth

The 340B program has expanded well beyond congressional intent in part because of administrative actions by HRSA and lack of appropriate oversight in four key areas, leading to unintended consequences:

1. Patient definition;
2. Hospital eligibility;
3. Hospital-purchased outpatient sites (called “child sites”); and
4. Contract pharmacies

These administrative actions and the unwillingness to course-correct, coupled with changes in the health system, have contributed to a transformation in the 340B program. As previously noted, today's program is unrecognizable in size and character as compared to the program that was created in 1992. And it's unrecognizable in many of its current effects—for instance, promoting consolidation of services under hospital ownership and the accompanying higher costs.

The change in the 340B program's size and character are seen in the following points:

- It took 15 years after 340B's enactment (2007) for annual 340B sales to reach \$3.9 billion. Yet in the next 9 years, between 2007 and 2016, 340B sales grew more than four-fold to \$16.2 billion at the 340B price.²³ The Medicare Payment Advisory Commission's (MedPAC) May 2015 Report to Congress provides data showing that between 2005 and 2013, 340B sales grew seven times faster than total U.S. medicine spending.²⁴
- In 2004, more than a decade after enactment, federal grantees accounted for 55 percent of 340B sales and hospitals accounted for 45 percent. By 2016, grantees' share of sales had dropped to just 13 percent while hospitals' share of 340B sales increased to 87 percent.²⁵ The clear majority of 340B sales to hospitals are to DSH hospitals, accounting for about 80 percent of 340B hospital sales.²⁶
- 340B purchases as a share of hospitals' total drug purchases (both inpatient and outpatient) inched above 10 percent in 2005, over a decade after the program began.²⁷ Over the next 11 years, 340B purchases as a share of hospitals' total drug purchases has consistently and steadily increased.²⁸

²³ A. Fein, “EXCLUSIVE: The 340B Program Hits \$16.2 Billion in 2016; Now 5% of U.S. Drug Market,” Drug Channels Blog, May 18, 2017.

²⁴ Analysis of data from [MedPAC, “Report to the Congress: Overview of the 340B Drug Pricing Program,” May 2015](#), pp. 11-12.

²⁵ Mathematica, *The PHS 340B Drug Pricing Program: Results of a Survey of Eligible Entities*, August 2004. Apexus, 340B Health Summer Conference, July 2016; Apexus, 340B Health Summer Conference, July 2016.

²⁶ Chris Hatwig, Apexus Update, 340B Health Summer Conference, 2016.

²⁷ A. Fein “340B Purchases Hit \$12 Billion in 2015 – and Almost Half of the Hospital Market,” Drug Channels Blog, February 23, 2016.

²⁸ A. Fein, “340B Purchases Were More than Half of the Hospital Market in 2016,” Drug Channels Blog, May 19, 2017.

- Between 1994 and 2016, the number of child sites increased from 34 to over 15,000.²⁹ While some of that growth is due to changes in guidance from HRSA regarding how 340B child sites should register for 340B, there was dramatic growth in the program even before that guidance changed. For example, a *Health Affairs* study found that “in 2011 there were 16,500 340B entity sites that were affiliated with approximately 3,200 unique 340B entities. That is roughly double the number of sites reported in 2001.”³⁰
- Between 2002 and 2017, the number of contract pharmacy arrangements increased from 279 to 51,963.³¹ Nearly 90 percent of the growth came after HRSA’s 2010 subregulatory guidance authorizing unlimited contract pharmacy networks. In 2017, two-thirds of contract pharmacy locations were owned by one of just a few large pharmacy chains.³²

The 340B Program Creates Market Distorting Incentives That Increase Consumer Prices for Medicines, Shift Care to More Expensive Hospital Settings and Accelerate Provider Consolidation

The 340B program is distorting the health care market by leading to higher costs for patients and payers, according to economists and independent government auditors. The program has been growing at an alarming rate that is poised to continue, absent needed changes.³³ It is likely that 340B market distortions will have an expanding influence if the program is left unchecked. Several factors described below are contributing to these unintended consequences.

Distorting market prices for prescription medicines

In an analysis of prescription medicine pricing published in the *New England Journal of Medicine*, economists at Harvard and the University of Chicago identified the 340B program as one factor that was leading to higher prescription medicine prices. These economists concluded that “lawmakers could lower the price of prescription drugs by reforming the federal 340B Drug Pricing Program. [...] The scope of the 340B program is currently so vast for drugs that are commonly infused or injected into patients by physicians that their prices are probably driven up for all consumers” (emphasis added).³⁴ Another study in *JAMA* noted that list prices for medicines are likely higher than they otherwise would be “to offset revenue losses incurred as a larger number of drug sales

²⁹ HRSA OPA Database, January 2017.

³⁰ R. Conti and P. Bach, “The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities,” *Health Affairs*, vol. 33 no. 10.

³¹ HRSA OPA Database, January 2017.

³² Chains included are Walgreens, Albertsons, Kroger, Rite Aid, Walmart and CVS. A. Fein, “The Booming 340B Contract Pharmacy Profits of Walgreens, CVS, Rite Aid, and Walmart,” *Drug Channels*, July 11, 2017.

³³ Aaron Vandervelde and Eleanor Blalock, “340B Program Sales Forecast: 2016 – 2021,” 2016, available at: <http://340breform.org/userfiles/December%202016%20BRG%20Growth%20Study.pdf> (accessed March 11, 2018).

³⁴ R. Conti and M. Rosenthal, “Pharmaceutical Policy Reform — Balancing Affordability with Incentives for Innovation,” *N Engl J Med* 2016; 374:703-706.

become eligible for 340B discounts (and thus fewer drugs are sold at full price).”³⁵

These economists’ concern that drug prices are being driven up for everyone because of the size of the 340B program is borne out by data analyzing the relative share of the 340B program. Overall, 340B sales accounted for about 8 percent of all branded outpatient drug sales in 2017, but certain therapeutic categories were disproportionately impacted.³⁶ For example, for certain types of cancer medicines, sales to 340B hospitals account for 33 percent of *all* Medicare Part B reimbursement.³⁷ 340B Health, which represents hospitals that participate in 340B, has erroneously reported that 340B discounts constitute a much smaller share of drug sales, but their analysis uses several methodological sleights of hand to artificially lower that number.³⁸ For example, they only include a portion of legally-mandated 340B discounts and artificially decrease the value of the 340B discounts they do include, and they compare 340B discounts to total net pharmaceutical sales—including generics—even though 340B discounts are largely concentrated in brand sales. They also ignore that 340B sales are heavily concentrated in certain therapeutic areas.

340B creates incentives that drive up spending on prescription medicines and undermine efforts to promote more efficient, high-quality care

A range of studies demonstrate that the 340B program is creating incentives for hospitals to drive up treatment costs. It has evolved into a vehicle for hospitals to keep markups earned from arbitrage: buying medicines at a legally mandated 340B ceiling price and reselling them at a higher price. This means that in many cases, the program has provided hospitals the opportunity and incentive to increase and maximize 340B revenue by either prescribing more medicines or more expensive medicines.

A 2015 GAO study investigated whether this incentive was leading to higher drug spending at 340B hospitals and found that “Medicare beneficiaries were prescribed more drugs, more expensive drugs, or both, at 340B DSH hospitals.”³⁹ The differences the GAO found “did not appear to be explained by the hospital or patient population

³⁵R. Conti, P. Bach, “Cost Consequences of the 340B Drug Discount Program,” *JAMA :The Journal of the American Medical Association*, 2013;309(19):1995-1996. doi:10.1001/jama.2013.4156.

³⁶ A. Vandervelde and E. Blalock, “Measuring the Relative Size of the 340B Program: 2012-2017,” Berkeley Research Group, July 2017.

³⁷ Drugs sold to 340B hospitals account for 33% of *all* Part B reimbursement for breast cancer and multiple myeloma drugs. A. Vandervelde and E. Blalock, “Measuring the Relative Size of the 340B Program: 2012-2017,” Berkeley Research Group, July 2017.

³⁸ A. Dobson, K. Murray, J.E. DaVanzo, “Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers” Dobson|DaVanzo for 340B Health, July 2017.

³⁹ Government Accountability Office, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442, June 2015.

characteristics.”⁴⁰ Instead, GAO suggested that the higher spending was likely due to the financial incentive to obtain more 340B revenue from patients having *higher* spending on medications.⁴¹

As noted earlier, a recent *New England Journal of Medicine* article found similar patterns in the areas of hematology-oncology and ophthalmology. Strikingly, the study also found that despite the increase in Medicare Part B spending on prescription drugs, DSH hospital eligibility for 340B was associated with “*lower proportions of low-income patients in hematology–oncology and ophthalmology and with no significant differences in hospital provision of safety-net or inpatient care for low-income groups or in mortality among low-income residents of the hospitals’ local service areas.*” (emphasis added)⁴² Thus, costs were higher at 340B hospitals, but these hospitals were not treating more low-income patients and were not achieving lower mortality rates for this vulnerable group.

While the Administration took a first step last year toward addressing these incentives in Part B with their changes in the hospital outpatient prospective payment system rule,⁴³ the same incentives that drive up costs continue to exist when hospitals serve patients insured in the commercial market. In fact, a study from the actuarial firm Milliman that used commercial market data found similar patterns to those GAO highlighted in Part B. That Milliman study found average per patient outpatient drug spending for commercially insured patients at 340B DSH hospitals is nearly three times the spending at non-340B DSH hospitals (\$457 and \$159, respectively) (emphasis added).⁴⁴ These cost differences are not explained by differences in overall health of populations treated at 340B and non-340B hospitals. Higher health care spending is ultimately paid by insurers and beneficiaries, who pay cost sharing and premiums. Thus, these results can be used to infer that the 340B program may be contributing to higher healthcare costs for everyone with private insurance through higher premiums and, for a smaller subset of patients, through higher out-of-pocket costs.

Many policymakers, including several Members of this committee, have publicly stated their interest in redesigning the health care system to create incentives for efficient and quality health care that rewards providers for outcomes of care, instead of volume of care provided. As these studies demonstrate, 340B is working at cross-purposes with those health care system goals by providing hospitals with a large revenue stream that is derived from perverse incentives that raise treatment costs.

⁴⁰ Ibid.

⁴¹ Ibid.

⁴² S. Desai and J.M. McWilliams, "Consequences of the 340B Drug Pricing Program," *N Engl J Med* 2018.

⁴³ 80 Fed Reg 59216, (Dec. 14, 2017).

⁴⁴ Milliman, "Commercial Payers Spend More on Hospital Outpatient Drugs at 340B Hospitals," March 2018.

Incentives that shift care from community-based physicians to more expensive settings

Many hospitals have further expanded their ability to generate revenue from 340B purchases by buying community-based physician practices and then obtaining 340B discounts for prescriptions written by those physicians. These acquired practices are often geographically located in wealthier areas than the 340B hospitals themselves⁴⁵ and have no requirement to treat uninsured or vulnerable patients. Increasingly, hospital acquisitions of independent community-based physician practices are leading to the closure of community cancer clinics across the country.⁴⁶ Care in hospital outpatient settings is notoriously more expensive overall. One study found hospitals charge five times their acquisition costs for medicines administered in the outpatient setting, and commercial payers reimburse these drugs at rates that are 252 percent of average hospital acquisition costs (without factoring in 340B discounts).⁴⁷ Because 340B hospitals acquire drugs at prices far below average, their charges and reimbursements are even higher compared to their acquisition costs.

In looking at cancer care specifically, an analysis by IMS Health found that average costs for administering cancer medicines are typically twice as high at hospital outpatient departments compared to community-based oncologists, which can lead to “higher patient cost responsibility.”⁴⁸ A recent article published in *JAMA Oncology* had similar findings and the authors note that “[w]hile patients may receive the same treatment in either setting, insurers typically reimburse payments to HOPDs [hospital outpatient departments] at a higher rate than to physician offices”⁴⁹ There is no evidence to suggest that differences in payment are attributable to patient characteristics or the type of care received.⁵⁰ Hospitals are able to receive higher payments than physician practices from commercial payers for the same services due to market power. This market power is often driven by vertical integration, specifically the purchase of oncology practices by hospitals and health systems, that gives hospitals leverage to charge higher prices when

⁴⁵ R. Conti and P. Bach, “The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities,” *Health Affairs*, vol. 33 no. 10.

⁴⁶ National Cancer Policy Forum; Board on Health Care Services; Institute of Medicine. *Ensuring Patient Access to Affordable Cancer Drugs: Workshop Summary*. Washington (DC): National Academies Press (US); 2014 Dec 23. Workshop Summary. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK268684/>; T. Hagen, “COA: Trend of Oncology Practice Closures, Consolidations Softens,” Nov. 2016.

⁴⁷ The Moran Company, “Hospital Charges and Reimbursement for Drugs: Analysis of Markups Relative to Acquisition Cost,” October 2017.

⁴⁸ IMS Institute for Healthcare Informatics. *Global Oncology Trend Report: A Review of 2015 and Outlook to 2020*, June 2016.

⁴⁹ A.N. Winn, N.L. Keating, J.G. Trogon, et al. “Spending by Commercial Insurers on Chemotherapy Based on Site of Care,” 2004-2014. *JAMA Oncology*. Published online February 22, 2018. doi:10.1001/jamaoncol.2017.5544.

⁵⁰ Wynn, Barbara O., Peter Hussey, and Teague Ruder. *Policy Options for Addressing Medicare Payment Differentials Across Ambulatory Settings*. Santa Monica, CA: RAND Corporation, 2011. Available at: https://www.rand.org/pubs/technical_reports/TR979.html

negotiating with commercial payers.⁵¹ Lee Newcomer (UnitedHealthcare) notes this when talking about hospital systems by stating that the hospitals can say, “If you want our beds, you have to take our prices for oncology treatment.”⁵²

Economists have concluded that 340B’s role in shifting care to more expensive settings will drive higher costs. For example, according to economists at the University of Minnesota, the current 340B program—if not changed—“will ultimately end up increasing health care costs for everyone, as patients are shifted from cheaper, community-based care to more expensive hospital settings....” (emphasis added).⁵³ Similarly, researchers at Memorial Sloan Kettering have noted that 340B is helping to drive consolidation of physician practices into hospitals and that in the absence of changes “the trend toward consolidation will continue to drive up the cost of commercial insurance....” (emphasis added).⁵⁴ Similarly, the recent Energy and Commerce report on 340B concludes that the 340B program has contributed to the marked increase in the consolidation of private oncology practices, that this consolidation is often profit driven, and “in some instances, negatively impacts the quality of patient care and can result in increased patient cost.”⁵⁵

A 2015 change to the Medicare statute designed to promote site neutrality⁵⁶ has led to most *new* off-campus provider-based sites being paid under the Physician Fee Schedule⁵⁷ instead of the hospital outpatient prospective payment system (OPPS). However, this change does not affect those grandfathered off-campus sites that were billing under OPPS before November 2, 2015,⁵⁸ which includes thousands of off-campus departments of 340B hospitals. Nor does this Medicare site neutral payment policy apply to commercial payers.

⁵¹ R.M. Conti, M.B Landrum, and M. Jacobson. “The impact of provider consolidation on outpatient prescription drug-based cancer care spending.” Available at: <http://www.healthcostinstitute.org/wp-content/uploads/2016/08/HCCI-Issue-Brief-Impact-of-Provider-Consolidation.pdf>

⁵² L.N. Newcomer. Those who pay have a say: A view on oncology drug pricing and reimbursement. *The Oncologist*. 2016 Jul 1;21(7):779-81.

⁵³ S.T. Parente and M. Ramlet, “Unprecedented Growth, Questionable Policy,” Carlson School of Management at University of Minnesota.

⁵⁴ P.B. Bach and R.H. Jain, “Physician’s Office and Hospital Outpatient Setting in Oncology: It’s About Prices, Not Use,” *Journal of Oncology Practice* 2017 13:1, 4-5.

⁵⁵ House Energy and Commerce Subcommittee on Oversight and Investigations, Review of the 340B Drug Pricing Program, January 10, 2018. Available at: https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf

⁵⁶ Social Security Act § 1833(t)(1)(A)(v), (21).

⁵⁷ These sites are paid under a special variant of the Physician Fee Schedule that CMS developed for the off-campus hospital facilities that no longer can bill under OPPS.

⁵⁸ Social Security Act § 1933(t)(21)(A)99).

Recent Administrative Action Is a Step Forward, But More Action Is Needed to Modernize the 340B Program

Mounting evidence from the GAO and other independent economists indicates that DSH hospitals' use of the 340B program is driving up health care costs,⁵⁹ has led to a steady drumbeat of calls to modernize the program. Members of the House and Senate have taken steps to do so by introducing three bills to provide needed reporting and accountability into how DSH hospitals use the 340B program.⁶⁰ These bills vary in their scope, but all three bills exempt rural-designated hospitals and 340B-eligible grantees from the new requirements, an exception that PhRMA supports. We agree with the authors of the legislation that the issue with abuse of the 340B program are not the grantees or rural hospitals, but large DSH hospitals and their associated child sites, many of which are in well-off communities.

One such piece of legislation is S. 2312, the Helping Ensure Low-income Patients have Access to Care and Treatment (HELP ACT) introduced by Sen. Cassidy. The HELP ACT includes many important and common-sense reporting and accountability measures that will help all stakeholders better understand how DSH hospitals are using the 340B program and which of their patients are accessing 340B discounts. This legislation also includes much-needed standards for how DSH hospitals and their child sites qualify for the 340B program, responding to findings from the GAO.⁶¹

In addition to congressional interest in increasing accountability in the 340B program, the Trump Administration has also sought to address concerns that 340B is increasing government and patient spending on physician administered medicines⁶² through changes in the Hospital Outpatient Prospective Payment System at 340B hospitals.⁶³ Their changes lower Medicare reimbursement for 340B medicines paid for under the Medicare Part B Hospital Outpatient Prospective Payment System.⁶⁴ This policy change is expected to reduce incentives created by the 340B program that may cause hospitals to administer more and higher cost medicines in Part B. While this change is an important first step,

⁵⁹ R. Conti, P. Bach, "Cost Consequences of the 340B Drug Discount Program," *JAMA : The Journal of the American Medical Association*, 2013;309(19):1995-1996. doi:10.1001/jama.2013.4156.; Government Accountability Office, Medicare Part B Drug; P. Bach and R.H. Jain, "Physician's Office and Hospital Outpatient Setting in Oncology: It's About Prices, Not Use," *Journal of Oncology Practice* 2017 13:1, 4-5."

⁶⁰ 340B PAUSE Act, H.R. 4710, 115th Cong. (2017); HELP ACT, S. 2312, 115th Cong. (2018); Ensuring the Value of the 340B Program Act of 2018, S. 2453, 115th Cong. (2018) H.R. 4570, S. 2312, and S.2453 (see detailed description later in testimony)

⁶¹ Government Accountability Office, "Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement," Sept. 2011.

⁶² Government Accountability Office, "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals," June 2015.

⁶³ 82 FR 52356

⁶⁴ 82 FR 52356.

Medicare Part B represents less than one-quarter of total hospital revenue from 340B.⁶⁵ Because half hospital’s total 340B revenue is derived from 340B physician administered medicines purchased by commercial payers and others outside of fee-for-service Part B, 340B’s incentives to drive up cost without adding value for patients remain intact.⁶⁶

Improvements to 340B are Urgently Needed in Five Key Issue Areas: 1) Patient Definition; 2) DSH Hospital Eligibility Standards; 3) Standards for Off-Site Hospital Clinics (“Child Sites”); 4) Contract Pharmacy Arrangements; and 5) Program Integrity

Issue Area 1: The 1996 patient definition should be clarified to better define who is entitled to manufacturer discounts on 340B medicines.

The 340B program was originally created to make prescription medicines more accessible to low-income, uninsured, and other vulnerable patients through safety-net facilities. Under the 340B law, a covered entity may only claim a 340B discount under the program if the medicine is used for the covered entity’s own “patient.”⁶⁷ The 340B law further prohibits covered entities from reselling or otherwise transferring medicines purchased under the 340B program to anyone but a “patient” of the covered entity (a practice commonly referred to as “diversion”).⁶⁸

Despite this centrality of “patient” to defining the program’s scope and assuring that statutory program integrity requirements are met, throughout the history of the 340B program, there has been a lack of meaningful standards as to when an individual qualifies as a “patient” of a covered entity. In fact, the current patient definition is more than two decades old despite how much the health care landscape in the United States has evolved during that time. This has contributed to well-documented program abuses and violations. For example, the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) observed in a report focused on contract pharmacy arrangements:

Covered entities . . . reported different methods of identifying 340B-eligible prescriptions, and in some cases their determinations of 340B eligibility differ from one covered entity to another for similar types of prescriptions. This suggests a lack of clarity on how HRSA’s patient definition should be applied in contract pharmacy arrangements. Covered entities appear to have differing interpretations of what HRSA guidance requires . . . there is

⁶⁵ A. Vandervelde and E. Blalock, “Site of Care Shift for Physician-Administered Drug Therapies,” Berkeley Research Group, Oct. 2017.

⁶⁶ A. Vandervelde and E. Blalock, “Site of Care Shift for Physician-Administered Drug Therapies,” Berkeley Research Group, Oct. 2017.

⁶⁷ 42 U.S.C. § 256b(a)(5)(b).

⁶⁸ 42 U.S.C. § 256b(a)(5)(B).

inconsistency within the 340B Program as to which prescriptions filled at contract pharmacies are treated as 340B-eligible.⁶⁹

Despite these concerns raised by government watchdog agencies, HRSA's patient definition has not been updated or modified since 1996, over twenty years ago.⁷⁰ As highlighted by HRSA itself along with GAO and OIG, the 1996 patient definition is vague and lacks the specificity needed to provide clear direction to covered entities and manufacturers about who is a patient for 340B discount purposes. This has allowed covered entities to take broad interpretations of the patient definition guidance and use 340B medicines for individuals who in many instances would not be considered true "patients" in any traditional sense of the word, i.e., someone who relies on a provider for ongoing and routine medical care.

Included in the 1996 patient definition is overly broad language that "the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or *other arrangements* (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity" (emphasis added).⁷¹ HRSA itself noted problems with the "other arrangements" language in its 2007 proposed patient definition clarification, which was never finalized:

"Some [hospitals] have been contracting with health care providers to create a loose affiliation model for outpatient health care services.... This model improperly seeks to expand the definition of a patient beyond that envisioned by Congress in prohibiting the resale of 340B drugs outside the eligible covered entity limits."⁷²

In 2011, GAO reported HRSA's own stated concern that the "other arrangements" language in the 1996 patient definition was too vague:

"HRSA officials told us that the definition currently includes individuals receiving health care services from providers affiliated with covered entities through "other arrangements," as long as the responsibility for care provided remains with the entity. However,

⁶⁹ OIG, Contract Pharmacy Arrangements in the 340B Program, OIE-05-13-00431 at 16. Feb. 2014.

⁷⁰ See 61 Fed. Reg. 55156 (Oct. 24, 1996). Under HRSA's current guidance, the patient definition requires that: (1) the covered entity have a relationship with the individual "such that the covered entity maintains records of the individual's health care"; (2) the individual receives health care services from a health care professional who is an employee of the entity or provides care under contract or other arrangements with the 340B entity, "such that responsibility for the care provided remains with the covered entity"; and (3) the individual receives care from the covered entity that is consistent with the service or range of services for which the entity receives federal grant funding or FQHC look-alike status (this requirement does not apply to DSH hospitals). An individual is not considered a patient of a covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug for subsequent self-administration or for administration in the home setting. Different criteria for defining "patients" apply to AIDS Drug Assistance Programs.

⁷¹ 61 Fed. Reg. at 55157

⁷² 72 Fed. Reg. at 1546-47 (emphasis added).

HRSA does not define “other arrangements,” and officials told us that what is meant by responsibility for care also needs to be clarified. Because of the lack of specificity in the guidance, the agency has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity . . . does not actually have the responsibility for care.”⁷³

Recommendations to improve the current patient definition

A clear definition of “patient” is required under the law and critical to the integrity and long-term sustainability of the 340B program. HRSA should update its 340B patient definition so that it has clear and enforceable standards for hospitals. A revised definition of a patient for 340B purposes should require that there is an established relationship between the hospital and the patient such that the patient receives medical care at the hospital’s onsite facilities registered with HRSA. HRSA has correctly recognized that an “individual’s health care relationship with the covered entity is the most important factor in determining” whether an individual is a patient of a 340B covered entity.⁷⁴ The patient definition should be more explicit about identifying the factors for which a hospital is responsible for an individual’s care and treatment, including documenting and maintaining medical records for an individual. These elements include:

1) Clear relationship between hospital and health care provider

A revised patient definition must make clear the relationship between the hospital and the health care professional seeing the patient. A revised patient definition should also eliminate the language in the 1996 patient definition referring to a patient as one who receives health care services from a provider under “contractual or other arrangements.” As discussed above, this loose “other arrangements” language has been a long-standing concern for GAO and HRSA due to the potential for abuse it creates.

HRSA should clarify in its patient definition that only an employee or independent contractor of the hospital are considered health care professionals who can treat a patient on behalf of the hospital. A provider connected to a hospital through a looser affiliation is not acting on behalf of the hospital and that provider’s patients are not the covered entity’s patients for 340B purposes.

⁷³ GAO, “Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvements,” Sept. 2011, supra, at 23.

⁷⁴ 72 Fed. Reg. at 1544.

2) *Location of services provided*

The revised definition also should make clear that a patient must receive outpatient care at a covered entity's facilities. This service should go beyond dispensing or administration of a medication and include the prescribing or administration of the medicine for which the covered entity receives a 340B discount. As HRSA has said in the past, this means discounts are not available when only dispensing discounted medicines to an individual for subsequent self-administration.⁷⁵

3) *Requirements for hospitals eligible through a government contract*

The revised patient definition should make clear that if the individual is receiving care from a covered entity that has a contract with a state or local government, such care must be within the scope of the contract that bestows that covered entity 340B eligibility under subsection (a)(4)(L)(ii) of the 340B statute (42 USC 256b). This would more closely align the patient definition for grantees (already subject to this element in the current patient definition) and DSH hospitals. It would also ensure that the patient remains an individual who receives services from a covered entity consistent with the reason why the entity is 340B eligible. For example, HRSA should specify that where a private nonprofit hospital is 340B eligible because it has a contract with a state or local government to care for low-income individuals ineligible for Medicare and Medicaid, a 340B patient of the hospital must receive services under that contract. Likewise, for a private nonprofit hospital that is 340B eligible because it has been formally granted governmental powers, a 340B patient of the hospital should be an individual who receives health care services furnished by the hospital in connection with its governmental powers.

Requiring that a patient of a 340B hospital receive the services for which Congress made the hospital 340B eligible would promote the purposes of the 340B law (to provide discounted medicines to a private nonprofit hospital that contracts to care for "low-income individuals who are not eligible for Medicaid or Medicare," but not for a private nonprofit hospital with "a minor contract to provide indigent care which represents an insignificant portion of its operating revenues").⁷⁶ It would also make the patient definition more symmetrical between grantees and hospitals.

HRSA has never sought to explain why it applied this principle to grantees but not hospitals, and we see no rational basis to treat covered entity grantees differently from hospitals on this important element of the definition of who is a 340B patient.

⁷⁵ 72 Fed. Reg. at 1544 ("An individual will not be considered a 'patient' of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self administration or administration in the home setting.").

⁷⁶ H.R. Rep. 102-384 (II) (1992), 12.

Accordingly, HRSA should specify in a revised definition that a patient of a private hospital that is 340B-eligible through a contract with a state or local government to care for low-income individuals ineligible for Medicare and Medicaid, must receive care under that contract. Similarly, the revised definition should specify that a hospital eligible because of “formally granted powers” can only receive discounts for patients who receive care in connection to such powers.

HRSA has authority to issue a revised patient definition

In 2015, in response to the criticism received around the program’s lack of clear standards, HRSA issued a proposed omnibus guidance covering many aspects of the 340B program, including changes to the patient definition. At that time, HRSA believed it had legal authority to issue guidance on a new patient definition, and we continue to believe that HRSA can issue a new patient definition without statutory rulemaking authority. Congress should encourage HRSA to exercise this authority or seek clarity from HRSA on areas where they think they lack authority. In general, PhRMA supported these proposed changes to the patient definition and believes finalizing such a definition would make important strides in clarifying the patient definition and resolving many of the inconsistencies in the way stakeholders have interpreted this key term. We appreciate HRSA’s efforts to spell out the elements of the patient definition, which are essential to ensuring compliance with the law regarding diversion and duplicate discounts and to maintaining overall program integrity. However, we believe there are some instances where entities—particularly small or rural covered entities and grantees—need additional flexibility from the proposed patient definition and should be allowed to continue to use the definition now in place given their focus on safety net populations.

Key Takeaway: The GAO, OIG and HRSA have all noted that the current patient definition is overly vague and allows DSH hospitals to obtain 340B discounts for patients who Congress never intended to qualify for the program. HRSA should finalize a new patient definition that, at a minimum, includes the important elements discussed above and makes exceptions for grantees. If HRSA does not release a new patient definition in short order, Congress should step in and create a new patient definition that reflects these important elements in statute.

Issue Area 2: Hospital eligibility standards are outdated, and the requirements in statute are not well enforced.

With 45 percent of all acute care hospitals participating in a program that was first intended for true safety-net facilities,⁷⁷ the eligibility criteria for DSH hospitals must be reexamined. While some of the eligibility standards are set in statute and Congress would have to intervene to

⁷⁷ MedPAC, “Report to the Congress: Overview of the 340B Drug Pricing Program,” May 2015.

update those criteria, HHS also has an important role to play in ensuring that only true safety-net hospitals are eligible for the 340B program.

Recommendations to improve DSH hospital eligibility standards

1) Revisiting the DSH Metric

Under the 340B statute, hospitals can qualify for the 340B program based in part on their DSH percentage,⁷⁸ an inpatient measure relating to the number of Medicaid and low-income Medicare patients treated in a hospital's inpatient unit. Paradoxically, this means that hospitals are *more* likely to qualify for 340B as more of their patients gain Medicaid coverage and are no longer uninsured. As discussed previously, more hospitals have become eligible for 340B due to significant expansions in Medicaid eligibility, which could not have been anticipated in 1992. In addition, a 340B DSH hospital designation has no direct relationship to the amount of care that a hospital provides to low income, indigent, or uninsured populations.

Analysis of the amount of charity care DSH hospitals provide points to the fact that some of these hospitals have a low charity care obligation. Hospitals report the amount of charity care they provide on their Medicare Cost Reports. Charity care is the cost of providing free or discounted care to low-income individuals who qualify for the hospital's charity care program. These programs are focused on helping low-income patients access health care that would otherwise be unaffordable. PhRMA believes it is important to examine the relative amount of charity care 340B hospitals provide as part of an examination of whether 340B eligibility is truly targeting true safety net hospitals. For example, according to hospitals' own data, 64 percent of 340B DSH hospitals provide a lower level of charity care than the national average for *all* hospitals.⁷⁹ This raises questions as to whether the DSH hospitals participating in the program are in fact the hospitals treating large numbers of vulnerable or uninsured patients. Additionally, in a 2015 report, the GAO found that there were "notable numbers" of 340B DSH hospitals that provided low amounts of charity care."⁸⁰ MedPAC also reported that it had found little correlation between hospitals' DSH adjustment percentages and whether they had either high-cost patients or a high percentage of uninsured patients.⁸¹ Finally, the 2018 Energy and Commerce report

⁷⁸ See 42 U.S.C. § 256b(a)(4)(L)-(O).

⁷⁹ Alliance for Integrity and Reform of 340B, "Benefiting Hospitals, Not Patients: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program," Spring 2016.

⁸⁰ Government Accountability Office, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442, June 2015.

⁸¹ Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy (Washington, DC: MedPAC, March 2007).

reached the conclusion that “it is unclear whether the DSH metric ensures that the program is available for hospitals that are truly serving a disproportionate share of uninsured and vulnerable patients.”⁸²

It is also important to note that because DSH is an *inpatient* measure being used to determine eligibility for the *outpatient* 340B program, it is not impacted when 340B hospitals add child sites that serve relatively wealthy patients. As noted above, analysis has shown that often these child sites are geographically located in wealthier areas than the DSH hospitals themselves.⁸³ The 2018 Energy and Commerce report issued a recommendation for reforms to the 340B program, suggesting that “Congress should reassess whether DSH is the appropriate measure for program eligibility, or whether a metric based on outpatient population would be more appropriate.”⁸⁴

These flaws in the DSH metric suggest that Congress should reexamine the eligibility criteria for 340B to better link eligibility for the program to an entity’s actual *provision* of a disproportionate share of outpatient charity care. Because hospitals already report charity care in their Medicare Cost Reports, such a metric could be relatively simple to operationalize.

2) *Revising Current Loose Eligibility Standards for Hospitals Not Owned or Operated by a State or Local Government*

All 340B hospitals must be owned or operated by a unit of state or local government or a private nonprofit hospital that (a) has been formally granted governmental powers by a state or local government; or (b) has a contract with a state or local government to provide health care services to low-income individuals who are not Medicare or Medicaid eligible. Unfortunately, there is little guidance, transparency, or oversight to enforce these requirements. In fact, HRSA does not even review or collect the contracts that make some hospitals eligible for 340B discounts. Instead, the responsibility falls on hospitals to self-report if they believe they no longer meet the requirements. GAO noted that “hospitals with contracts that provide a small amount of care to low-income individuals not eligible for Medicare or Medicaid

⁸² House Energy and Commerce Subcommittee on Oversight and Investigations, Review of the 340B Drug Pricing Program, January 10, 2018. Available at: https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf

⁸³ R. Conti and P. Bach, “The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities,” *Health Affairs*, vol. 33 no. 10.

⁸⁴ House Energy and Commerce Subcommittee on Oversight and Investigations, Review of the 340B Drug Pricing Program, January 10, 2018. Available at: https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf

could claim 340B discounts, which may not be what the agency intended.”⁸⁵ This lack of oversight makes it difficult to ensure that contracts are meeting congressional intent. The legislative history states that a private nonprofit hospital that had “a minor contract to provide indigent care which represents an insignificant portion of its operating revenues” could not qualify for 340B under the state and local government contract test.⁸⁶ Yet HRSA is not enforcing this requirement which could easily be done routinely when HRSA recertifies a hospital’s 340B eligibility.

At a minimum, HRSA should collect these contracts and post them online. Strong and transparent standards are needed for private DSH hospitals’ contracts that confer 340B eligibility. These contracts should not be minor contracts and instead should represent a sizable investment of hospital resources. Similarly, HRSA should set clear standards for how hospitals qualify for 340B if they have been formally granted “governmental powers.” The governmental powers that confer 340B eligibility to a hospital should be made publicly available by each hospital. Merely providing health care services is not sufficient to meet this standard.

Recently introduced legislation offers important improvements in hospital reporting requirements

Several Members of Congress have recently introduced bipartisan legislation to address some of the deficiencies in hospital reporting and accountability. S. 2312, the HELP ACT would impose reporting requirements on DSH, cancer and children’s hospitals that increase the understanding of how the program is used. For example, these hospitals would report the insurance status of patients who receive 340B medicines. This will show whether uninsured patients are receiving 340B medicines both at the DSH hospital itself and separately for each child site. The HELP ACT would also strengthen government oversight with GAO and OIG reports on key areas in need of being revisited, including an evaluation into the state and local government contracts that bestow 340B eligibility on certain private DSH hospitals. The legislation would also implement clear eligibility standards for private DSH, children’s and cancer hospitals and their offsite outpatient facilities. Representatives Larry Bucshon and Scott Peters have introduced legislation, H.R. 4570, the 340B PAUSE Act, that would take many similar steps to increase understanding of how 340B hospitals qualify for the program and which patients are receiving 340B prescriptions. Both bills also include a commonsense temporary moratorium on the enrollment of new DSH hospitals while data is being collected.

The commonsense reporting requirements included in the HELP ACT and 340B PAUSE Act are focused on basic information hospitals are likely already collecting for other purposes. For example, the data on the insurance status of patients already is needed for payment purposes.

⁸⁵ *Manufacturer Discounts in the 340 Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept.2011), p 23.

⁸⁶ U.S. House of Representatives Report accompanying H.R. Rep. 102-384 (II) (1992).

Further, the data requirements included in both pieces of legislation are in line with the level of reporting already required of many grantees as a condition of the federal grants they receive. Federal grantees, like Ryan White clinics, are already subject to additional HRSA oversight as a federal grantee. Importantly, in its January 2018 report on the 340B program, the House Energy and Commerce Subcommittee on Oversight and Investigations interviewed numerous HRSA grantees who told the committee that “they found the additional [340B] program requirements manageable.”⁸⁷

Key Takeaway: The current lax DSH hospital eligibility standards are contributing to the growth of 340B that has led to higher costs for patients and the health care system. Both Congress and HRSA should update the current eligibility criteria for DSH hospitals. Specifically, Congress should review the use of the DSH metric and HRSA should develop and enforce eligibility standards for hospitals not owned or operated by a state or local government.

Issue Area 3: Current guidance on eligibility criteria for child sites is outdated and is driving up costs and should be updated.

The 340B law defines the types of hospitals that can participate in the program with great specificity⁸⁸ but never mentions participation of off-campus outpatient facilities associated with these hospitals (also known as child sites). Although there is no basis in the statute for including these sites, in 1994, HRSA unilaterally issued guidance dramatically expanding the 340B program by permitting child sites to participate—even if as hospitals have interpreted, they are only loosely connected to the parent hospital and do not serve a needy population.⁸⁹ Child sites have become a major source of the program’s growth and incentives. In 1994, there were a total of 34 child sites. By 2016 this had increased to over 15,000.⁹⁰

These hospital child sites are a key factor accounting for the 340B program’s explosive growth and its shift away from the program’s original goal of helping get discounted medicines to uninsured and vulnerable patients.⁹¹ For example, a 2014 *Health Affairs* study found that child sites are converting 340B “from [a program] that serves vulnerable communities to one that enriches hospitals.”⁹² The authors of a recent *New England Journal of Medicine* Perspective on 340B state that “hospitals have purchased community practices in part ... to expand their

⁸⁷ House Energy and Commerce Subcommittee on Oversight and Investigations, Review of the 340B Drug Pricing Program, January 10, 2018. Available at: https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf

⁸⁸ 42 U.S.C. § 256b(a)(4)(L)-(O).

⁸⁹ 59 Fed. Reg. 47884, 47885 (September 19, 1994).

⁹⁰ HRSA OPA Database, October 2016.

⁹¹ A. Vandervelde and E. Blalock, “340B Program Sales Forecast: 2016 – 2021,” 2016, available at: <http://340breform.org/userfiles/December%202016%20BRG%20Growth%20Study.pdf> (accessed March 11, 2018).

⁹² Rena M. Conti and Peter B. Bach. The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities, *Health Affairs* 33, no. 10 (2014): 1786-1792.

footprint into wealthier neighborhoods to ‘profit’ from the 340B program.”⁹³ As discussed earlier in this testimony, hospitals purchasing physician practices leads to higher costs for many payers and other patients because commercial reimbursement for hospital-owned practices are typically higher due to their market power.⁹⁴

Recommendation for addressing concerns with child sites

1) Implement new eligibility standards and requirements for child sites

At a minimum, HRSA should revisit its 1994 guidance given the rampant growth in the number of child sites, the lack of any requirements that these clinics serve a safety-net role and the evidence that they are leading to higher costs for many patients. Congress, too, should consider revising the current child site eligibility rules.

The new standards for child site eligibility should be developed to help prevent 340B from being an incentive for the broad consolidation of community-based providers, which drives up health care costs. Child sites should also be required to provide a broad range of services and have a sliding fee scale that shares 340B discounts with low-income patients.

Recently introduced legislation takes an important first step to improve hospital reporting requirements for child sites

Both the HELP ACT and the 340B PAUSE Act would help improve visibility into how child sites are using the 340B program by requiring hospitals to report insurance status of the patients treated at each child site and the costs of charity care provided at each site. Currently, there is no data available about the patients treated at child sites, and as discussed above, these patients are not factored into the hospital’s DSH metric. Such data will be valuable in determining whether child sites are serving communities in need of safety-net services.

Both bills also include a commonsense temporary moratorium on the enrollment of new child sites while data is being collected. The HELP ACT would also require that a child site of any 340B DSH, children’s or free-standing cancer hospital meet several requirements, including adhering to the charity care policy and any sliding fee scale of its parent hospital. These new standards would help ensure that patients directly benefit from 340B discounts at the child site.

⁹³http://www.nejm.org/doi/full/10.1056/NEJMp1716139?query=recirc_curatedRelated_article

⁹⁴ As discussed earlier, while the administration recently made changes to address 340B hospitals’ incentives to increase spending in Medicare Part B, that change will likely have a minimal impact on incentives for future provider consolidation. The new Part B reimbursement changes are by definition limited to the less than one quarter of DSH hospitals’ 340B profits derived from Part B fee-for-service sales and the new policy will not impact newly acquired outpatient sites that are not paid under the Outpatient Prospective Payment System.

Key Takeaway: The current eligibility criteria for offsite outpatient facilities (“child sites”) associated with 340B DSH hospitals are leading to consolidation that raises health care costs and increasing the presence of 340B sites in wealthy areas, which is not consistent with the program’s mission. Criteria must be revised and new reporting requirements must be implemented to ensure these sites are serving communities that need safety-net services.

Issue Area 4: Rampant growth of hospital use of contract pharmacy arrangements must be reined in through updated guidance.

Contract pharmacies are for-profit, retail pharmacies that 340B hospitals partner with to dispense 340B medicines to patients of the covered entity who fill prescriptions at the pharmacy. The contract pharmacy and the hospital then share the profit generated through the distribution of a 340B discounted medicine, with no guarantee that patients benefit from the 340B discount.

The 1992 statute creating the 340B program did not authorize or even mention contract pharmacies. To address requests from covered entities without an in-house pharmacy, HRSA issued guidance in 1996 allowing covered entities without an on-site pharmacy to contract with one off-site pharmacy.⁹⁵ In 2010, the use of contract pharmacies was dramatically expanded through Obama Administration sub-regulatory guidance.⁹⁶ The 2010 guidance eliminated the one pharmacy limitation and permitted 340B entities that have an on-site pharmacy to also use an unlimited number of contract pharmacies. This change dramatically increased the number of contract pharmacies but did nothing to ensure that patients benefitted from this expansion. A 2014 report by the OIG stated that at the time, “the number of unique pharmacies serving as 340B contract pharmacies has grown by 770 percent, and the total number of contract pharmacy arrangements has grown by 1,245 percent” since 2010.⁹⁷ In 2017, there were more than 50,000 contract pharmacy arrangements.⁹⁸

There is no evidence patients consistently benefit from contract pharmacies

Pharmacies can generate higher returns by dispensing 340B prescriptions than non-340B prescriptions, however uninsured patients are not always offered the 340B discounted price at contract pharmacies.⁹⁹ Despite the fact that the 340B program was designed to ensure increased access to prescription medicines for vulnerable or uninsured patients, the 2014 OIG report found that the majority of hospitals in their study did not ensure that they passed 340B discounts back to uninsured patients who filled their prescriptions at a contract pharmacy.¹⁰⁰ In contrast, the grantee covered entities in the OIG study were more likely to have developed systems for their

⁹⁵ Fed. Reg. Vol. 61, No. 165.

⁹⁶ Fed. Reg Vol. 75, No 43.

⁹⁷ HHS Office of the Inspector General, “Contract Pharmacy Arrangements in the 340B Program,” Feb. 2014.

⁹⁸ HRSA OPA Database, March 2017.

⁹⁹ HHS Office of the Inspector General, “Contract Pharmacy Arrangements in the 340B Program,” Feb. 2014.

¹⁰⁰ HHS Office of the Inspector General, “Contract Pharmacy Arrangements in the 340B Program,” Feb. 2014.

contract pharmacies to pass 340B discounts on to uninsured patients.¹⁰¹ Additionally, 340B Health, the trade association representing 340B hospitals, has stated that contract pharmacies are typically unable to determine who is eligible for 340B discounts at the time a prescription is filled. In a letter to New York State, 340B Health stated, “the overwhelming majority of these [contract] pharmacies do not know at the time a claim is processed whether or not it relates to a 340B drug.”¹⁰²

Recommendations for reining in contract pharmacy arrangements

1) Increase and improve HRSA oversight of the contract pharmacy program

HRSA’s oversight of 340B, and particularly the contract pharmacy program, is insufficient. In 2012, as part of its efforts to improve 340B program integrity, HRSA began conducting covered entity audits. Many of these audits focus on covered entities’ usage of contract pharmacies, however they are limited in scope and the fact that they continue to result in adverse findings demonstrates that audits are not enough to ensure program integrity.

While the 2010 HRSA contract pharmacy guidance recommends that covered entities perform annual independent audits of their contract pharmacies, in practice, this guidance has not resulted in meaningful action on the part of covered entities. The 2014 HHS OIG report on contract pharmacies found that “[f]ew covered entities reported retaining independent auditors for their contract pharmacy arrangements as recommended in HRSA guidance.” HRSA’s current approach to overseeing contract pharmacy arrangements relies heavily on this covered entity self-policing, yet there are no rules in place that compel processes that would ensure compliance with the 340B statute. The OIG report states that covered entities must notify HRSA if they find that duplicate discounts or diversion have occurred in their contract pharmacy arrangements, however OIG found that only 7 of 30 covered entities they reviewed even reported that they retained HRSA’s recommended independent auditors, let alone reported findings of diversion or duplicate discounts. OIG’s overall assessment of the current state of the contract pharmacy program was that “without adequate oversight, the complication created by contract pharmacy arrangements may introduce vulnerabilities to the 340B program.” This level of self-policing and the lack of a framework for program compliance is not appropriate for such a large (and growing) aspect of the 340B program. We urge HRSA to focus its audits efforts on contract pharmacy arrangements with DSH hospitals, given that these hospitals represent 80 percent of 340B sales and rely on arrangements that make them more vulnerable to possible diversion of 340B discounts to non-patients.

¹⁰¹ Ibid.

¹⁰² Safety Net Hospitals for Pharmaceutical Access Dec. 19, 2011 letter to Jason A. Helgerson, Medicaid Director & Deputy Commissioner Office of Health Insurance Programs, New York State Department of Health.

Additionally, HRSA currently has no oversight efforts of covered entity arrangements with the 340B services providers (e.g., third party administrators or TPAs) who manage most of the back-end administration of the 340B program. Instead, as discussed above, HRSA cites its recommendations that covered entities conduct independent audits to ensure compliance in these arrangements. But the lack of clear program rules and a reliance on this covered entity self-policing approach has been insufficient to ensure the integrity and the intended patient impact of the 340B program.

2) *Revise lax regulations that have enabled middlemen to benefit from the contract pharmacy program*

Contract pharmacy expansion is a troubling example of middlemen diverting resources from 340B's intended purpose of assisting low-income or vulnerable patients. An industry of for-profit pharmacies and their third-party administrators and consultants has developed since 2010 with the goal of maximizing 340B dispensing. Their only apparent motive is to financially benefit from taking a share of the markup between the legally mandated 340B price and the higher price paid by patients and insurers.

There are multiple examples of the third-party marketing strategies that boast of the revenues they can help hospitals generate through expanded use of contract pharmacies. In 2013, the LinkedIn profile of a Walgreens employee came to Senator Grassley's attention. In his profile, the employee boasts about Walgreens' ability to help clients "Generate revenue from your 340B patients."¹⁰³ Senator Grassley's subsequent letter to the Walgreens CEO seeking additional information about Walgreens' participation in 340B sums up the problem with the contract pharmacy program succinctly, as he states, the 340B program "is not intended to subsidize pharmacies that team up with covered entities to turn a profit."¹⁰⁴

Additionally, other third-party vendors like Talyst, a for-profit vendor which provides a software platform for pharmacies, make 340B profitability the cornerstone of their sales pitch to prospective contract pharmacy clients. Talyst tries to sell its services by telling clients that 340B drugs generate higher pharmacy markups than non-340B drugs and that Talyst is the one to help them leverage that profit potential, while underscoring that savings don't need to be passed through to patients.¹⁰⁵ In fact, Talyst highlights that "the covered entities are allowed to use the benefit of these substantial savings in any way they choose." Talyst is one of hundreds of for-profit middlemen taking a cut of a program designed to help the safety-net population. Little

¹⁰³ The link has been taken down but it was previously at <http://www.linkedin.com/pub/timothy-hong/28/651/511>

¹⁰⁴ Senator Charles Grassley, Letter to Walgreens CEO Gregory Watson, July 21, 2013. Available at: http://www.pembrokeconsulting.com/pdfs/Grassley_340B_Letter_to_Walgreens_31July2013.pdf

¹⁰⁵ http://www.talyst.com/wp-content/uploads/Talyst_White_Paper_Benefit_Becoming_Contract_Pharmacy.pdf

to no oversight exists to monitor contract pharmacies and these third-party vendors. HRSA and Congress must take steps to determine how and if patients are benefitting.

3) *Address 340B program integrity concerns driven by the contract pharmacy program*

The contract pharmacy program inherently raises program integrity concerns. A 2014 OIG report found that contract pharmacy arrangements make it more difficult for HRSA and others to identify diversion and duplicate discounts.¹⁰⁶ The 340B program prohibits covered entities from purchasing a medicine at a 340B discount that generates a Medicaid rebate claim.¹⁰⁷ Consequently, the law creates an absolute prohibition on duplicate discounts. However, despite this clear statutory imperative, current prevention methods do not stop or prevent duplicate discounts. The increasing use of contract pharmacies coupled with expansion of Medicaid rebates for medicines used by Medicaid Managed Care Organization (MCO) enrollees have exacerbated the problem of duplicate discounts — with HRSA and the Centers for Medicare & Medicaid Services (CMS) thus far not taking effective steps to prevent this statutory violation. In fact, HRSA released 2014 guidance that expressly excluded Medicaid managed care utilization from the only mechanism HRSA has developed to prevent duplicate discounts (the Medicaid Exclusion File), stating that it “recognizes the need to address covered entities’ role in preventing duplicate discounts under Medicaid Managed Care, and is working with CMS to develop policy in this regard.”¹⁰⁸ As of 2018, this policy has yet to be developed. This leaves a critical gap in enforcing the law’s duplicate discount ban as about 55 million Americans are covered by Medicaid managed care plans. Half of all Medicaid spending on prescription medicines was through MCOs in 2014¹⁰⁹ and that share has likely increased in recent years.

Continued expansion of 340B contract pharmacy arrangements is expected to keep driving growth in the 340B program. Due to several factors, under current law, it is projected that by 2023, contract pharmacy utilization will exceed \$10 billion of the estimated \$31.5 billion in sales at the 340B price.¹¹⁰ This growth comes against a

¹⁰⁶ HHS Office of the Inspector General, “Contract Pharmacy Arrangements in the 340B Program,” Feb. 2014.

¹⁰⁷ 42 U.S.C. § 256b(a)(5)(A).

¹⁰⁸ HRSA, 340B Drug Pricing Program Release No. 2014-1 (Dec. 12, 2014). The Medicaid Exclusion File mechanism requires that 340B covered entities either “carve in” (provide 340B drugs to Medicaid patients and report this practice to HRSA, so that these entities are listed on the Exclusion File and State Medicaid programs do not bill manufacturers for rebates on drugs furnished by these entities) or “carve out” (do not provide 340B drugs to Medicaid beneficiaries, so that drugs supplied by a 340B entity to a Medicaid patient triggers a Medicaid rebate, but not a 340B discount). Under the 2014 guidance, this mechanism no longer applies to prevent double discounts on 340B drugs provided to MCO beneficiaries.

¹⁰⁹ KFF, “Total Medicaid Managed Care Enrollment, 2014” available at: <https://www.kff.org/medicaid/state-indicator/total-medicaid-mc->

[enrollment/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D](https://www.kff.org/medicaid/state-indicator/total-medicaid-mc-enrollment/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D) (accessed March 11, 2018); MACPAC, “Medicaid Spending for Prescription Drugs,” January 2016. Available at: <https://www.macpac.gov/wp-content/uploads/2016/01/Medicaid-Spending-for-Prescription-Drugs.pdf>.

¹¹⁰ Berkeley Research Group unpublished estimates for PhRMA, December 2017.

backdrop of a contract pharmacy program operating in a largely unregulated environment.¹¹¹

Key Takeaway: The current unlimited use of contract pharmacies by hospitals is not sustainable and diverts savings from 340B to for-profit pharmacies and other middlemen. There is also no evidence that contract pharmacies are directly benefiting patients. HRSA should revisit its current contract pharmacy policy for hospitals. Any new policy must consider what role, if any, hospitals' contract pharmacies should play in a program that has grown significantly over the past eight years.

Issue Area 5: Better enforcement is needed of current 340B program rules and guidance.

Given the important role that the 340B program plays in the health care safety net, it is imperative that participants have a clear understanding of the program's requirements and are adhering to the program's statutory requirements. Unfortunately, this is not common practice.

Six years ago, in 2012, as part of agency-wide efforts to improve program integrity, HRSA began covered entity and manufacturer audits. The FY 2017 HRSA data show that two-thirds of all DSH hospitals audited were noncompliant in at least one area and many were noncompliant in multiple areas.¹¹² Currently, there are no real repercussions for hospitals if they are found to be noncompliant with program guidelines. For example, hospitals that obtain 340B discounts for which they were not eligible may have to pay back those discounts, but there are no additional penalties that would create a true incentive to diligently prevent duplicate discounting or diversion. To date, we are not aware of any covered entity HRSA has terminated for violation of 340B program rules.

Additionally, the current lack of clear program standards makes it difficult to conduct meaningful audits of covered entities. As mentioned earlier in this testimony, the OIG and GAO continue to state that the current definition of a 340B patient lacks specificity, leading to program integrity issues. While HRSA audits for incidences of diversion, it is unclear what HRSA is auditing for since there are not sufficiently clear standards for who constitutes a 340B patient.

A recent paper from the Berkeley Research Group shows that the 340B program more than doubled in size from 2010 to 2015. BRG predicts that exponential growth will continue for at least the next five years. At current staffing levels, each HRSA auditor will be responsible for providing oversight of an average of \$1B in drug purchases at over 4,000 distinct covered entity or contract pharmacy locations by 2021.¹¹³

Similar to our earlier comments specific to contract pharmacy, we urge HRSA to focus its audits on contract pharmacy arrangements with DSH hospitals, given that they represent 80 percent of

¹¹¹ A. Vandervelde and E. Blalock, "340B Program Sales Forecast: 2016-2021," BRG, December 2016.

¹¹² HRSA OPA Database Program Integrity FY17 Audit Results (Accessed March 6, 2018).

¹¹³ A. Vandervelde and E. Blalock, "340B Program Sales Forecast: 2016 – 2021," 2016, available at: <http://340breform.org/userfiles/December%202016%20BRG%20Growth%20Study.pdf> (accessed March 11, 2018).

340B sales and rely on arrangements that make them more vulnerable to possible diversion of 340B discounts to non-patients.

Key Takeaway: A lack of clear and enforceable standards combined with no adverse consequences for entities that violate 340B requirements mean that the hospital audits currently taking place do not assure program compliance. HRSA and Congress should consider ways to improve clarity and enforcement of program rules.

Changes are Needed to Previous Administration Proposals for the 340B Drug Ceiling Price and Manufacturer Civil Monetary Penalties Regulation

The 340B Drug Ceiling Price and Manufacturer Civil Monetary Penalties (CMP) Regulation, developed under the Obama Administration, was set to go into effect on March 6, 2017, with enforcement scheduled for April 1, 2017. Due to the widespread concerns it raised, the final rule's effective date has been delayed four times since the Trump Administration took office in January 2017.¹¹⁴

Last fall, HRSA delayed the effective date of the 340B Ceiling Price and CMP Rule until July 1, 2018. In the notice announcing the delay, HRSA stated that it intends to engage in further rulemaking on issues covered in the rule. PhRMA supports rulemaking on this issue, but we believe any HRSA rule must be consistent with the statute and not impose undue burdens on manufacturers. Our concerns with the previous ceiling price/CMP regulations are outlined below.

Problems with the delayed ceiling price and CMP regulation

- 1) *Penny pricing*: One key concern PhRMA has with the delayed rule is that it finalizes a 340B program “penny pricing” policy, which would require biopharmaceutical manufacturers to effectively give away their medicines to covered entities for free by permitting a manufacturer to only charge a penny in many cases. Penny pricing typically occurs in specific instances when the 340B ceiling price formula results in a zero 340B ceiling price for a particular medicine. The statutory formula for a medicine's 340B ceiling price is a medicine's average manufacturer price (AMP) minus its Medicaid rebate. When a medicine's Medicare rebate equals its AMP, the resulting 340B ceiling price is zero. The 340B statute cannot be read as requiring manufacturers to “sell” their medicines for a penny to 340B entities, because under the law, the discount only applies to bona fide “purchases.” However, we note that forced transfers of medicines at 1 cent to covered entities are not true “purchases.” Further, penny pricing creates incentives for 340B entities to stockpile medicines, which can create artificial shortages that make it difficult for patients to get the medications they need.

¹¹⁴ Delays were issued on 3/21/2017, 5/22/2017, 10/1/2017, and 7/1/2018.

In PhRMA’s comment letters to HRSA, we suggested three reasonable alternatives to penny pricing: the prior quarter (non-penny) 340B ceiling price, the Federal Ceiling Price or nominal price – which manufacturers could use as their 340B ceiling prices instead of a penny price. These alternatives would give effect to the statutory language limiting the 340B statute to true “purchases” – not forced transfers.

- 2) *Refund Requirements*: The delayed rule includes two separate sets of administratively burdensome refund requirements. Under the first refund requirement, manufacturers must estimate 340B prices for new medicines and then make refunds to all 340B covered entities that purchased the new medicine during its initial quarters on the market if a recalculated “actual” ceiling price turns out to be lower than the “estimated” ceiling prices. Under the second refund requirement, manufacturers must recalculate 340B ceiling prices from past quarters based on restatements of Medicaid rebate metrics and then initiate and make refunds to covered entities on past sales based on the recalculated ceiling price. Both refund requirements would call for manufacturers to make costly changes to their pricing systems and business procedures to come into compliance and waste manufacturer resources due to their needless complexity.

The delayed rule also requires manufacturers to pay refunds to 340B covered entities without subtracting any amounts that the covered entity owes to the manufacturer (unless the entity voluntarily agrees to the offset, which seems unlikely). This policy in effect would require a manufacturer to pay a covered entity more than it owes to the entity. Companies cannot be required to pay more than they owe; this policy is wrong, was not authorized by the 340B law and needs further review.

- 3) *CMPs*: Finally, this delayed rule would permit the OIG to impose CMPs against manufacturers without specifying any clear standards for imposing these penalties. This omission heightens risk for manufacturers that already are operating in a complex program lacking clear ground rules. The 340B statute, as amended by the Patient Protection and Affordable Care Act (ACA), authorizes CMPs against a manufacturer that “knowingly and intentionally charges a covered entity a price for purchase of a medicine that exceeds the [340B ceiling] price” (up to \$5,000 for each “instance” of overcharging), provided that CMPs “shall be assessed according to standards established in regulations.”¹¹⁵

The delayed rule failed to establish standards for assessing CMPs. For one thing, it does not even define “knowingly and intentionally.” HRSA instead gives unfettered discretion to OIG to define “knowing and intentionally.” The resulting uncertainty will cause manufacturers unnecessary costs, as the Final Rule essentially concedes,

¹¹⁵ 42 U.S.C. 256b(d)(1)(B)(vi) (emphasis added).

and will not satisfy the statute’s requirements for “standards established in regulations.”¹¹⁶

Separately, PhRMA wishes to note our support for HRSA finalizing and launching a new password-protected website that would provide a secure way for 340B covered entities to access ceiling prices. Some of our members were involved in testing this system and we urge HRSA to launch this website as soon as possible, with appropriate safeguards given the sensitive nature of the pricing information that will be available on the website. The ACA requires that this site be developed,¹¹⁷ and we look forward to covered entities having confidential access to this information.

In Summary, PhRMA Urges Action to Bring the 340B Program in Line with the Current Health Care System and Ensure Its Sustainability for the Future

PhRMA strongly believes that the 340B program should continue, and we recognize how the program helps support true safety net entities and their patients that currently rely on the program. However, we urge both Congress and the Administration to make changes to the program so that its structure and rules are consistent with its roots as a safety-net program and serve the mission of supporting access to care for uninsured or vulnerable patients.

Currently DSH hospitals’ use of the program is not serving that mission. Instead, economists are finding that the 340B program is raising costs for all patients and that low-income patients are not seeing better health outcomes at 340B hospitals. They suggest these higher costs are due to three reasons: 1) hospitals earn more 340B revenue when patients take more medicines and more expensive medicines; 2) 340B is contributing to the shift in care from community-based physicians to more expensive hospital outpatient facilities; and 3) the large share of 340B-discounted medicines purchased by hospitals for certain conditions is driving up prices. To make matters worse, hospitals do not have to pass along 340B savings to low-income patients or even make them aware of the discounts. This means that uninsured or vulnerable patients may be *worse off* due to the 340B program.

These market distortions are due in part to the lack of clear program standards that would limit 340B eligibility to true safety-net hospitals and the patients who rely on these hospitals for their care. Instead, a combination of guidance that is either vague or overly broad coupled with a lack of HRSA oversight has fueled dramatic growth in the program. Unfortunately, none of this growth seems focused on ensuring that patients benefit. Instead, this growth is centered on increasing profits for hospitals, retail pharmacies and middlemen.

¹¹⁶ 42 U.S.C. § 256b(d).

¹¹⁷ PPACCA § 7102(d)(1)(B)(iii).

PhRMA once again thanks this committee for its interest in the 340B program. We urge you to continue taking a closer look at this program, encouraging HHS and HRSA to fully consider their oversight responsibilities and authorities, and to consider critical legislative changes to the 340B program, not only to increase transparency and reporting, but also to ensure the program is being executed in a way consistent with its original intent that benefits patients, the safety net, and the health care system as a whole.