SNHPA

Safety Net Hospitals for Pharmaceutical Access

Statement of Safety Net Hospitals for Pharmaceutical Access
Before the U.S. House Energy and Commerce Subcommittee on Health

Hearing on Examining the 340B Program

March 24, 2015

On behalf of over 1,000 member hospitals and health systems that participate in the 340B program, Safety Net Hospitals for Pharmaceutical Access (SNHPA) appreciates the opportunity to submit this statement to the House Energy and Commerce Health Subcommittee as it examines the 340B program.

Congress enacted the 340B drug discount program in November 1992 with broad bipartisan support to provide discounted prices on outpatient drugs for safety net providers serving high volumes of low-income patients. Today's witnesses have explained how the program works and the narrow categories of safety net providers that are eligible to participate, known as "covered entities," that serve the nation's most vulnerable patient populations. These providers serve tens of millions of uninsured and underinsured people every year. Despite the significant benefits 340B provides to safety net providers and their patients, 340B spending accounts for just 2% of total drug spending.

In addition to hospitals, covered entities also include several other types of safety net providers, such as community health centers, state and local health departments, HIV clinics and hemophilia treatment centers. Only a select number of hospitals are eligible to participate in the 340B program and receive discounts on drugs. To be in 340B, hospitals must either have a high caseload of Medicaid and/or low-income Medicare patients or be a small hospital located in a rural area. All non-profit hospitals in the 340B program must also have a contract with their state or local government to provide health care services to low-income individuals who do not have Medicaid or Medicare. Congress expanded the program in 2010 to new categories of hospitals. Although this change resulted in nearly doubling the number of hospitals that participate in 340B, the vast majority of the new hospitals are rural critical access hospitals with 25 beds or less. The newly-eligible hospitals account for just 3% of 340B spending. In contrast to the increase in the number of these small rural hospitals in 340B, the number of Medicare disproportionate share (DSH) hospitals in 340B has actually declined by 4% since 2012. Despite the decline, DSH hospitals participating in 340B provide more than twice as much care to

Medicaid and low-income Medicare patients as non-340B DSH hospitals, and nearly twice as much uncompensated care.[1]

The Health Resources and Services Administration (HRSA) has been in charge of overseeing and implementing the 340B program for the past 23 years. HRSA has consistently made clear that 340B is intended to help providers stretch scarce resources and is not a direct patient drug discount program or a benefit for insurers. Indeed, the 340B statute contains no such limiting language. As explained by HRSA in 2005:

> The purpose of the 340B Program is to lower the cost of acquiring covered outpatient drugs for selected health care providers so that they can stretch their resources in order to serve more patients or improve services . . . If the covered entities were not able to access resources freed up by the drug discounts when they apply for grants and bill private health insurance, their programs would receive no assistance from the enactment of section 340B and there would be no incentive for them to become covered entities."[2]

I. The 340B Program Allows Safety Net Providers to Supply More Services to More Low Income Patients

For 23 years, 340B's mission has been to lower drug costs for safety net providers so they can provide more comprehensive services and reach more individuals, as specified in the statute's legislative history. The House Committee report accompanying the 340B statute states that the 340B program is designed "to enable these entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[3] The program lets providers choose the best ways to serve their communities by using program savings from manufacturers, rather than tapping into federal funding. By not prescribing specific limits on the use of 340B savings, the statute relies on providers to identify the needs of their patients so that they can decide how to best target their resources.

The 340B program is meeting that mission. Some of the documented ways that 340B hospitals use 340B consistent with the program's intent include: providing free or reduced-cost medication to patients, helping patients use medications properly, caring for more patients, and offsetting losses from treating low-income patients.[4]

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[1] SNHPA, Analysis: 340B DSH Hospitals Have High Low-Income Patient Loads and Provide Significant Uncompensated Care, http://www.snhpa.org/340b-resources/why-340b-matters/340b-dsh-hospital-safety-net-role.

[2] HRSA, Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act (July 2005), *available at:* http://www.hrsa.gov/hemophiliatreatment/340Bmanual.htm (last accessed March 6, 2015).

[3] H.R. Rep. 102-384, pt. 2, at 12 (1992).

[4] *See e.g.*, GAO, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (Sept. 2011), *at* http://www.gao.gov/assets/330/323702.pdf [hereinafter "GAO Report"]; Madeline C. Wallack and Suzanne B. Herzog, Demonstrating the Value of the 340B Program to Safety Net Hospitals and the Vulnerable Patients They Serve (June 29, 2011) (Value of the 340B Program), *at* http://www.snhpa.org/images/uploads/340B_Value_Report_06-29-11.pdf.

Below are descriptions from several of our members as to how they use their 340B savings:

- The 340B program allows us to provide free or discounted medications and vaccinations to our community. 340B savings allowed us to provide Zyvox to an uninsured patient at no charge for six weeks of osteomyelitis. This totaled approximately $12,500 in assistance. We were able to provide expensive insulin to a patient at a greatly discounted rate. The patient had never been able to afford this medication prior to our assistance. In 2013, due to budget cuts, our local health department could not offer the annual flu "round up" for our area. We then stepped in and held the flu "round up" on campus, providing some vaccines and a majority of labor to staff the vaccination push. Last month, our out-patient pharmacy pharmacists and technicians went to our local homeless shelter and provided free flu vaccines.

- The 340B program helps us provide low-cost drugs to uninsured individuals and a variety of critical health care services to our community. We provide ambulance services covering four counties. We offer three walk-in clinics that are open seven days a week. When another hospital in the community closed last fall, we took over their retail pharmacy operations. It is the only pharmacy in the community, but would not be financially sustainable on its own. 340B funding helps to make this service available for the residents of our town who do not have the means to travel to a larger community for prescription services. We offer a variety of specialty clinics, including cardiology, neurology, pulmonology, rheumatology, and urology. Our payer mix for these services is very poor, with many patients using our clinics who were unable to find providers that take Medicaid or uninsured patients. We care for over 1,100 Medicaid patients with chronic health conditions, which has resulted in a significant improvement in health status and a significant reduction in emergency room visits and inpatient hospitalizations.

- The 340B program helps to provide programs to help our community. Through the 340B program, we are able to give sliding fee scale discounts to patients. We also use 340B savings to fund an in-school dental program for children who do not have access to dental care.

II. The 340B Program is Needed Now More Than Ever

Congress created the 340B program to address unintended consequences that resulted from the enactment of the Medicaid Drug Rebate Program (MDRP) as part of the Omnibus Budget Reconciliation Act (OBRA) of 1990. Prior to OBRA 90, manufacturers provided voluntary discounts to many public health care providers and large-volume private purchasers. However, the MDRP required manufactures to pay a rebate to Medicaid to ensure that Medicaid had access to the "best price" on the market for a drug. The amount of the rebate was to be the difference between a manufacturer's average price of a drug and the "best price" for which the manufacturer sold the drug on the market, i.e. the lowest price. Therefore, manufacturers now had an incentive to make the gap between a drug's average price and "best price" to be as small as possible to reduce their rebate burdens. Instead of narrowing the gap by lowering their average prices, however, manufacturers increased their "best prices" by ceasing to offer discounted prices to hospitals and other drug purchasers. In 1992, Congress recognized the

increased drug costs that safety net providers were incurring while caring for the nation's most vulnerable individuals and created the 340B program to allow these providers to stretch their resources to provide more care to more patients.

Twenty-three years later, the 340B program continues to allow safety net providers to meet the needs of their low-income and vulnerable patient populations. The 340B program will continue to be of vital importance to safety net hospitals in the coming years for a number of reasons. First, even after a complete implementation of the Affordable Care Act (ACA) expands health coverage to uninsured Americans, millions of Americans will remain uninsured and will turn to safety net providers for care. Although the ACA is expected to reduce the number of uninsured individuals in the U.S., the Congressional Budget Office (CBO) estimates that 27 million people will remain uninsured in 2025.[5] The uninsured and underinsured will continue to turn to 340B hospitals after ACA is fully implemented and safety net providers will continue to rely on 340B savings to fulfill their missions.

Second, safety net hospitals are losing vital resources as ACA implementation continues, and it is becoming clear that hospitals will face higher uncompensated care costs than initially anticipated when Congress enacted the ACA. Congress enacted cuts in hospital DSH payments in the ACA under the premise that uninsured Americans would gain insurance coverage after the full implementation, thereby reducing hospitals' uncompensated costs.[6] Between fiscal year (FY) 2014 and FY 2019, Medicare DSH payments will decline by $22.1 billion, or by about 28 percent.[7] Medicaid DSH cuts will total $14.1 billion by FY 2019, or 50 percent.[8]

However, assessments of how many Americans will remain uninsured after ACA-implementation changed after the Supreme Court's ruling on the ACA made Medicaid expansion in the states voluntary. Studies are now acknowledging that Medicaid expansion will not lead to as much increased coverage as initially projected, which will likely result in higher uncompensated care costs for hospitals than initially estimated.[9] America's Essential Hospitals estimates that the shortfall in health care coverage created by a partial Medicaid expansion could result in $53.3 billion more in uncompensated care than expected when Congress passed the

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[5] CBO, Insurance Coverage Provisions of the Affordable Care Act—CBO's March 2015 Baseline (March 2015), *available at:* https://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2015-03-ACAtables.pdf.

[6] American Hospital Association, Medicare DSH Fact Sheet (Aug. 16, 2014), http://www.aha.org/content/13/fs-dsh.pdf.

[7] American Hospital Association, Medicare DSH Fact Sheet (Aug. 16, 2014), http://www.aha.org/content/13/fs-dsh.pdf; Teresa A. Coughlin, John Holahan, Kyle Caswell and Megan McGrath, An Estimated $84.9 Billion in Uncompensated Care Was Provided in 2013; ACA Payment Cuts Could Challenge Providers, Health Affairs, 33, no.5 (2014): 807-814, *available at:* http://content.healthaffairs.org/content/33/5/807.full.html.

[8] America's Essential Hospitals, Need for a Sustainable Solution: Restoring the Balance In Safety Net Financing (Oct. 2012), *available at:* http://essentialhospitals.org/wp-content/uploads/2014/10/NAPH_uncompensated_care_analysis_FINAL.pdf; Teresa A. Coughlin, John Holahan, Kyle Caswell and Megan McGrath, An Estimated $84.9 Billion in Uncompensated Care Was Provided in 2013; ACA Payment Cuts Could Challenge Providers, Health Affairs, 33, no.5 (2014): 807-814, *available at:* http://content.healthaffairs.org/content/33/5/807.full.html.

[9] Teresa A. Coughlin, John Holahan, Kyle Caswell and Megan McGrath, An Estimated $84.9 Billion in Uncompensated Care Was Provided in 2013; ACA Payment Cuts Could Challenge Providers, Health Affairs, 33, no.5 (2014): 807-814, *available at:* http://content.healthaffairs.org/content/33/5/807.full.html.

ACA.[10] A June 2014 Health Affairs study of a group of California hospitals found that between planned cuts to Medicaid DSH payments and inflation in health care costs, the hospitals will face significant funding gaps.[11] The study found that decreases in uncompensated care due to increased insurance coverage may not match the DSH cuts because of a continued high uninsured rate, Medicaid under-reimbursement, and high medical cost inflation.[12] As hospitals navigate through this post-ACA world, the 340B program will continue to support their mission and enable them to meet their patients' needs.

Third, as a result of Medicaid expansion under the ACA, safety net providers will serve a disproportionate share of newly-eligible Medicaid beneficiaries, and hospitals will rely on their 340B savings to treat these patients. The experience in Massachusetts shows what is already happening at the national level. After the state expanded insurance coverage, low-income individuals who were previously uninsured became covered by public insurance. However, many of these vulnerable patients continued to seek care from safety net providers, citing the convenience and affordability of safety net providers, as well as the availability of non-medical services, as reasons.[13] As 340B hospitals continue to treat large numbers of newly-eligible Medicaid beneficiaries, Medicaid will continue to reimburse safety-net providers at inadequate rates. The 340B program will help hospitals offset their unreimbursed costs and serve this vulnerable patient population.

Lastly, without 340B, drug manufacturers would once again have no incentive to offer discounted drug prices to safety net providers. This outcome would be especially problematic in today's health care environment, given the astronomical drug prices providers face. While the drug industry makes considerable profits, safety net providers continue to face significant challenges treating our nation's most vulnerable patients, often without reimbursement, and providing unprofitable services that other hospitals do not provide. Small rural hospitals throughout the country struggle to keep their doors open. Without their 340B savings, many of these hospitals would close. That would force their patients to travel significant distances to receive care, resulting in negative health outcomes.

III. Existing HRSA Guidance Needs Clarification

Both the Government Accountability Office (GAO) and the HHS Office of the Inspector General (OIG) noted concerns with HRSA guidance for manufacturers and covered entities, especially in the area of defining patients that are eligible for 340B. HRSA announced plans to issue

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[10] America's Essential Hospitals, Need for a Sustainable Solution: Restoring the Balance In Safety Net Financing (Oct. 2012), *available at:* http://essentialhospitals.org/wpcontent/uploads/2014/10/NAPH_uncompensated_care_analysis_FINAL.pdf.

[11] Katherine Neuhausen, Anna C. Davis, Jack Needleman, Robert H. Brook, David Zingmond and Dylan H. Roby, "Disproportionate-Share Hospital Payment Reductions May Threaten The Financial Stability Of Safety-Net Hospitals," Health Affairs, 33, no.6 (2014):988-996, *available at*: http://essentialhospitals.org/wp-content/uploads/2014/06/Health-Aff-2014-Neuhausen-988-96.pdf.

[12] *Id.*

[13] Leighton Ku, et al., Safety Net Providers After Health Care Reform: Lessons from Massachusetts, 171(15) ARCH. INTERN. MED. 1379 (Aug. 8, 2011), available *at* http://archinte.jamanetwork.com/article.aspx?articleid=1105879. *See also* Mark A. Hall, *The Costs and Adequacy of Safety Net Access for the Uninsured (Boston, Massachusetts)*, Robert Wood Johnson Foundation (June 2010), available *at* http://ww.newpublichealth.org/content/dam/supplementary-assets/2010/06/safetynetmass201006.pdf.

comprehensive guidance that affects both manufacturers and covered entities. Entities have been able to work with HRSA guidance during the 23 years the program has been in existence. In recent years, however, numerous stakeholders have sought clarification of guidance HRSA issued nearly 20 years ago. HRSA has announced that it will release comprehensive guidance in 2015 that will address the areas raised by both the GAO and the OIG. Stakeholders will need time to analyze this proposed guidance to determine its implications for the future of the 340B program.

Though HRSA has not yet issued updated guidance, it has taken steps to clarify certain existing policies. For example, there are hundreds of Frequently Asked Questions and Answers on the HRSA website and that of its contractor, Apexus, which address numerous policy questions. HRSA has also conducted numerous webinars that are intended to provide education on key policy issues, such as the criteria for defining eligible patients.

IV. Manufacturer Compliance with 340B Requirements

Past reports by the OIG and the GAO, as well as recent statements by manufacturers, cause concern regarding manufacturer compliance with 340B requirements. The OIG has issued multiple reports on the accuracy of 340B prices charged to covered entities, finding a significant pattern of overcharges, inadequate oversight by HRSA, and inability of covered entities to police the issue themselves. Specifically, the OIG found that most drug manufacturers were overcharging most 340B providers, with covered entities being overcharged for 14% of total purchases.[14] In fact, 68 out of 70 sampled entities paid more than they should have for 340B drugs. Some of the largest overpayments were due to manufacturer noncompliance with HRSA's policy setting the 340B price at a penny when the formula for calculating the 340B price results in a negative number, which is the result when a manufacturer increases the price of a drug significantly faster than the rate of inflation.

The OIG also found that HRSA did not have accurate information to allow for the proper calculation of ceiling prices, so that it would not be able to correctly identify or quantify overpayments.[15] The OIG further found that covered entities are prohibited by confidentiality provisions from evaluating the accuracy of the 340B prices they are charged by manufacturers.[16]

Following the OIG's reports, Congress enacted a series of manufacturer program integrity measures, which HRSA has not yet implemented, though it has announced that it is working to implement them. In the meantime, hospitals have no way of confirming whether manufacturers have fixed the problems that led to the significant overpayments identified in the OIG's report. Hospitals have no reason to believe that this significant pattern of overpayments is not continuing today.

The GAO also noted concerns in its 2011 report relating to potential discrimination against 340B covered entities by manufacturers. HRSA's current guidance on this issue does not include the

[14] HHS OIG, Review of 340B Prices, OEI-05-02-00073 (July 2006), *available at* http://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf.
[15] HHS OIG, Deficiencies in the Oversight of the 340B Drug Pricing Program, OEI-05-02-00072 (Oct. 2005), *available at:* http://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf.
[16] *Id.*

GAO's recommendation to require review of manufacturers' plans to restrict distribution of 340B discounted drugs.

HRSA has issued guidance on the 340B provision relating to the 340B pricing for orphan drugs that are used by rural and cancer hospitals. According to HRSA's policy, the 340B statute does not permit rural and cancer 340B hospitals to access 340B pricing for orphan drugs that are used to treat the orphan purpose for which they received their orphan designation. Several manufacturers have publicly stated that they do not intend to comply with HRSA's guidance.

Since the OIG has not updated its earlier reports and HRSA has not published the results of any manufacturer audits, it is impossible to know the state of compliance among manufacturers with basic 340B requirements such as offering 340B pricing on their outpatient drugs, setting the 340B ceiling price, implementing HRSA's penny pricing policy, and ensuring that its restricted distribution polices do not discriminate against 340B providers. To date, despite conducting almost 300 provider audits, HRSA has audited just one manufacturer and the results of that audit have not been released.

III. Oversight of Covered Entities in the 340B Program

The 2011 GAO report recommended that HRSA conduct audits of covered entities. Within just three months, HRSA auditors were at covered entity locations conducting audits. Nearly 300 risk-based and targeted audits have been completed since 2012. The vast majority of those audits are of hospital participants. Though not a single hospital has been removed from 340B due to an audit, some audit findings show that program requirements around defining which patients qualify for 340B should be clearer. Both the GAO and the OIG made similar recommendations and HRSA has announced plans to address this issue in its upcoming guidance. In addition, HRSA began implementing in 2012 a process whereby covered entities must annually certify to their compliance with program requirements and ensure that their information on the HRSA website is accurate.

IV. Use of Contract Pharmacies

In 2010, HRSA expanded an eleven-year-old policy allowing covered entities that did not have an in-house pharmacy to contract with an outside pharmacy to provide drugs purchased at 340B prices for their patients. Under the current policy, covered entities may contract with multiple pharmacies in their communities. As part of this new policy, HRSA imposed significant oversight responsibilities on covered entities to ensure that these contract pharmacy relationships comply with 340B requirements. For example, HRSA requires covered entities to establish tracking mechanisms and recommends that covered entities conduct independent annual audits of their contract pharmacy relationships, though rather than requiring such audits, HRSA leaves the exact method of compliance up to the covered entity.[17]

[17] Final Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272, 10278 (March 5, 2010), *available at:* http://hrsa.gov/opa/programrequirements/federalregisternotices/contractpharmacyservices030510.pdf.

In its 2014 report, the OIG interviewed 30 covered entities about their use of 340B contract pharmacies and found that providers take compliance seriously, but providers have different understandings of what HRSA guidance requires. Every provider the OIG interviewed had a system to limit 340B use to eligible patients. However, the OIG found that providers have different understandings of program guidance, particularly regarding defining eligible patients and identifying 340B drugs given to Medicaid managed care beneficiaries. HRSA will address these areas in upcoming guidance.

The OIG found that not all hospitals it interviewed in 2013 gave discounts on prescriptions to uninsured patients in their contract pharmacies. However, many more hospitals give discounts to the uninsured at contract pharmacies than reported by the OIG. In response to a 2015 survey, SNHPA member hospitals with contract pharmacy arrangements reported that many of them were giving discounts to the uninsured through their contract pharmacies.[18] The survey responses also documented that many hospitals had operational difficulties initially in identifying the uninsured, and they have since been able to address that problem. According to the survey:

- Two-thirds of hospitals with contract pharmacies give discounts to the uninsured at one or more of these pharmacies. The majority of those that do not cite operational difficulties.

- 23% of those that now give discounts to the uninsured at contract pharmacies said they did not do so initially, mainly due to operational difficulties.

Regardless of a hospital's ability to provide discounts in the contract pharmacy setting, hospitals use contract pharmacy savings to help their vulnerable patients. Some of the documented ways that hospitals use 340B consistent with the program's intent include: helping patients use medications properly, caring for more patients, and offsetting losses from treating low-income patients.

V. 340B and the Medicare Part B Program

Some have questioned whether Medicare Part B should reimburse 340B hospitals for separately-paid drugs less than what Medicare pays non-340B hospitals. Since the beginning of the 340B program, Medicare has always paid 340B hospitals for these drugs at the same rates they pay non-340B hospitals because doing so is consistent with the purpose of 340B. The program is intended to provide safety net hospitals with savings to help them better serve their vulnerable patients, and 340B has never been run as a benefit to insurers.

Over the years, the government has looked into the appropriateness of Medicare paying 340B hospitals the same as non-340B hospitals on two occasions. Each time, the conclusion was that it is appropriate for 340B hospitals to receive the same rates as non-340B hospitals. In 2008, the Centers for Medicare and Medicaid Services (CMS) requested information on the impact of 340B discounts on Part B hospital Outpatient Prospective Payment System (OPPS) rates for separately-paid drugs and asked whether Medicare should pay 340B hospitals at an adjusted rate

[18] SNHPA, Results of SNHPA Member Hospital Contract Pharmacy Survey (March 20, 2015), http://www.snhpa.org/news/contract-pharmacy-survey.

because they have lower drug acquisition costs than non-340B hospitals.[19] SNHPA and other organizations, including pharmaceutical companies, explained that 340B hospitals should receive the same level of reimbursement as non-340B hospitals because that is how Congress intended for 340B to operate.[20]

For example, Bayer submitted comments urging CMS not to pay 340B hospitals a lower amount, noting that:

> "[W]e do not believe it was the intent of Congress to leverage these steep [340B] discounts into lower Medicare reimbursement rates for those safety net providers serving the neediest populations. Because Congress intended the difference between payor, including Medicare, reimbursement rates and 340B acquisition prices to fund 340B covered entities' provision of safety net services, CMS' policy in establishing HOPD reimbursement rates directly undermines Congress' intent in the creation of the 340B program. We, therefore, urge the Secretary to exclude 340B prices in any calculation of AAC [actual acquisition cost] in setting SCOD payment rates."[21]

Novartis also submitted comments to CMS opposing separate reimbursement rates for 340B hospitals:

> "We also believe that it was not the intent of Congress when establishing the 340B program to create a system that would penalize participating hospitals from benefiting from these lower drug acquisition costs. There is ample evidence to indicate that Congress intended 340B participating hospitals to benefit from the lower acquisition cost of drugs and then use such savings to support expansion of other services to the disadvantaged population which they serve."[22]

Organizations representing oncologists also submitted comments to CMS opposing lower 340B reimbursement rates, including the Association of Community Cancer Centers (ACCC) and the American Society of Clinical Oncologists (ASCO). ASCO wrote to CMS saying it "does not believe that lowering reimbursement for Disproportionate Share Hospitals (DSH hospitals) and other entities receiving the 340B discounts would be appropriate. The 340B program was designed to aid these hospitals in serving needy Americans and these hospitals should not be penalized for receiving the 340B discount."[23]

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[19] Final Rule, Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates, 73 Fed. Reg. 68502, 68655 (Nov. 18, 2008).

[20] *See e.g.*, Letter from Sarah Creviston, Vice President Global Government Affairs, Baxter Healthcare to Kerry N Weems, Acting Administrator, CMS (Dec. 19, 2008); Letter from Ronald Dei Cas, Senior Director Government Relations, Novartis Oncology and Novartis Pharmaceuticals Corporation to Kerry N. Weems, Acting Administrator, CMS (Dec. 22, 2008).

[21] Letter from Sarah Creviston, Vice President Global Government Affairs, Baxter Healthcare to Kerry N Weems, Acting Administrator, CMS (Dec. 19, 2008).

[22] Letter from Ronald Dei Cas, Senior Director Government Relations, Novartis Oncology and Novartis Pharmaceuticals Corporation to Kerry N. Weems, Acting Administrator, CMS (Dec. 22, 2008).

[23] Letter from Joseph S. Bailes, Chair, ASCO Government Relations Council to Kerry Weems, Acting Administrator, CMS (Dec. 29, 2008).

The CMS Ambulatory Payment Classification Panel (APC Panel), which CMS relies upon to make payment determinations, noted in its February 2009 report that most commenters believed 340B hospitals should receive the same payment rates as non-340B hospitals.[24] The APC Panel recommended that if CMS continued to use its statutory authority to estimate acquisition costs to determine reimbursement, instead of relying on survey data, CMS should "pay 340B hospitals in the same manner as it pays non-340B hospitals."[25] CMS published its 2010 OPPS rates in November 2009 and accepted the Panel's recommendation.[26] CMS wrote, "Commenters on the CY 2009 OPPS/ASC final rule with comment period were generally opposed to differential payment for hospitals based on their 340B participation status. . . ."[27]

The issue of Medicare payments to 340B hospitals was raised again in October 2010 by the Department of Health and Human Services Office of Inspector General (OIG). The OIG issued a memorandum that looked into whether Medicare should pay the same rates to 340B and non-340B hospitals even though 340B hospitals pay less for drugs.[28] The OIG concluded that Medicare payments exceeding acquisition costs for 340B hospitals "was an expected result given the purpose of the 340B Program."[29] The OIG confirmed that the purpose of 340B is for hospitals to use their 340B savings — the difference between reimbursement rates and lower acquisition costs — to help serve their low-income patients. The OIG noted that 340B hospitals receive reimbursement rates that are higher than their acquisition costs "based on the fact that the populations served by these entities are disproportionately low-income, uninsured, and underinsured."[30]

SNHPA conducted a survey in 2013 of 340B hospitals to determine the impact on their ability to treat low-income patients if they had to pass their 340B savings on to Medicare. The survey found:

- 37% of respondents would drop out of 340B, and an additional 35% said they were unsure if they would withdraw.
- The majority of respondents reported a payer mix with a high percentage of Part B patients, showing that a reduction in Medicare reimbursement would have a significant impact on these hospitals. A requirement that these hospitals pass their 340B savings on to Medicare would diminish access and quality of care for low-income patients, including low-income Medicare beneficiaries.

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[24] CMS Advisory Panel on Ambulatory Payment Classification Groups, APC Panel Meeting Report, February 18–19, 2009, *available at:* http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/APC-Panel-Archives-Items/CMS1237161.html?DLPage=2&DLSort=0&DLSortDir=ascending (hereinafter "APC Panel Meeting Report").
[25] APC Panel Meeting Report, p. 29.
[26] Final Rule, Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates, 74 Fed. Reg. 60316, 60501 (Nov. 20, 2009).
[27] *Id.*
[28] Letter to Donald M. Berwick, Administrator, CMS from Stuart Wright, Deputy Inspector General for Evaluations and Inspections, HHS OIG (Oct. 22, 2012), available at http://oig.hhs.gov/oei/reports/oei-03-09-00420.pdf (last visited March 2, 2015) (hereinafter "OIG Memo").
[29] *Id.*
[30] *Id.*

- 95% of respondents said they would experience significant administrative or operational challenges, depending on how Medicare required hospitals to pass on their 340B savings.

A loss of 340B savings – either for hospitals that withdraw from 340B or for hospitals that continue to participate but face reduced payment rates – would mean hospitals would not be able to maintain the services they currently provide to their low-income patients. Hospitals provided testimony in response to our survey about what the impact would be on access and quality of care for their low-income patients. One hospital said, "This would make the 340B Program obsolete. It would greatly diminish services to the noninsured, and more importantly to the underinsured and indigent populations." Another hospital reported, "It would significantly reduce the amount of care that we could pass on to the indigent or underinsured patients. More likely is that we would get out of the 340B program." A third hospital said, "We will lay off workers and close departments. It will cause vulnerable patients to travel, so they won't receive care."

There have also been concerns raised related to Medicare Part B that hospitals are acquiring or affiliating with oncology practices and converting them into hospital outpatient departments. There is a nationwide increase in hospital acquisitions of community practices due to several widely-documented trends, and there is no evidence that the 340B program is responsible for the shift in oncology care from community practices to hospital settings.[31] Moreover, with 340B accounting for only 2% of the total drug market, it is unlikely that the 340B program is having such a widespread impact on the nation's health system. Regardless, data shows that hospitals treat patients who are poorer and sicker than patients treated by community oncologists. According to a 2012 biopharmaceutical consulting report, only 4% of patients treated by community oncologists were uninsured and only 4% were Medicaid.[32] In addition, 76% of patients referred by community oncologists to outside practices were low-income or underinsured, whereas only 12% had commercial insurance.[33]

In contrast, to participate in 340B, hospitals must treat a high level of Medicaid or low-income Medicare patients—roughly a 30% caseload—or be in a rural area, and these hospitals provide health care services, including oncology services, regardless of a patient's financial or insurance status. As compared to cancer patients treated in physician offices, hospital cancer patients are more likely to be self-pay, charity care, or on Medicaid; from lower-income, higher-poverty areas with lower college education rates; and more likely to suffer from severe chronic conditions.[34]

VI. Conclusion

[31] Maureen Testoni and Charles Hart, Drug Discount Analysis Misses The Mark, Health Affairs Blog (Oct. 8, 2014), *available at:* http://healthaffairs.org/blog/2014/10/08/drug-discount-analysis-misses-the-mark/.
[32] Lujing Wang, *et al*, *Turning Tides: Trends in Oncology Market Access*, *at* http://www.campbellalliance.com/articles/Campbell%20Alliance%20-%20Turning%20Tides%20-%20August%202012.pdf.
[33] *Id.*
[34] Berna Demiralp, Delia Belausteguigoitia, Qian Zhang and Lane Koenig, "Comparison of Cancer Patients Treated in Hospital Outpatient Departments and Physician Offices, Final Report," (Nov. 13, 2014), *available at:* http://www.aha.org/content/14/14hopdcancertrxreport.pdf (last visited March 4, 2015).

SNHPA appreciates the opportunity to submit this statement to the House Energy and Commerce Health Subcommittee. The 340B program is a vital lifeline for safety net hospitals and allows them to meet their mission to treat the low-income and vulnerable patients they serve. Hospitals will continue to rely on 340B as safety net providers struggle to meet their patients' needs. As the subcommittee examines the 340B program, please do not hesitate to contact us with any questions about 340B. You can reach SNHPA Senior Vice President and General Counsel Maureen Testoni at 202-552-5851 or maureen.testoni@snhpa.org.