AHPA
ADVENTIST HEALTH
POLICY ASSOCIATION

July 16, 2018

VIA ELECTRONIC MAIL
regulations.gov

Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: RIN 0991–ZA49, HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Mr. Azar:

On behalf of the Adventist Health Policy Association (AHPA), we appreciate the opportunity to comment on the Department of Health and Human Services (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. Our organization is the policy voice of five Seventh-day Adventist affiliated health systems that include 83 hospitals and more than 300 other health facilities in 17 states and the District of Columbia.

AHPA represents a major segment of the U.S. hospital sector. Our member hospitals operate in a variety of settings, ranging from rural Appalachia to urban areas of California. With such diverse facilities, populations served and geographical locations, we strive to provide an objective and sound policy voice that works across health care providers.

AHPA applauds the Administration for its efforts to tackle the rising costs of health care. We believe that comprehensive approaches need to be developed to truly lower drug prices and reduce patients' out-of-pocket costs. Simply reducing reimbursement rates will not lead to lower drug prices. It will leave safety-net hospitals with lower margins and higher costs, leading to reduced access for vulnerable communities as drug prices remain high.

We have read the Blueprint provided by HHS and developed the comments below. AHPA's comments are focused on the 340B program but also address other questions posed by the Agency regarding how to lower drug prices.

The 340B Program and Drug Prices

In the Blueprint, the Agency infers that the 340B program is contributing to increased drug prices. We disagree and urge the Agency to consider the following four areas addressed in the comments below:

- The Statutory Intent of the 340B Program
- The Relationship between the 340B Program and Drug Prices
- Scrutiny Over the 340B Program for Hospitals
- The Growth of the 340B Program

The Statutory Intent of the 340B Program

To understand the purpose of the 340B program, the Agency must consider its statutory intent. In 1992, Congress created the program to help safety-net hospitals "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] Congress recognized that high drug costs were depleting providers' budgets and threatening their ability to improve access for vulnerable communities. Therefore, the immediate beneficiaries of the 340B program are its covered entities. The 340B savings allow safety-net hospitals to stretch scarce Federal resources by providing more charity care, community benefit programs and clinical services that would otherwise not be available.

While we welcome the opportunity to improve the 340B program, we believe there is value in the program's original intent to help safety-net hospitals reach eligible patients. Therefore, policy changes should align with the statutory intent. **Reducing the 340B program's discounts would run counter to Congress' intent. It would constrain the financial ability of covered entities to support a range of high cost services that are often provided to vulnerable patients for little or no payment.** Hospitals make significant investments to ensure compliance with the program, such as maintaining complex billing processes and implanting sufficient technologies to comply with the program rules. Implementing further payment reductions puts more strain on hospitals participating in the program. Further cuts to the 340B program would also threaten the financial viability of entities such as Federally Qualified Health Centers, Ryan White clinics and hospitals serving rural communities. This will lead to the loss of access for many vulnerable patients that rely on these entities for health care.

[1] H.R. Rep. No. 102-384(II), at 12 (1992).

The Relationship Between the 340B Program and Drug Prices

AHPA believes that the focus on the 340B program as part of a strategy to reduce drug costs is misplaced. A study performed by Dobson DaVanzo & Associates recently found that the 340B program accounts for only 1-2 percent of the pharmaceutical industry's spending.[2] It accounts for 78 percent less than what drug manufacturers spend on marketing and 89 percent less than rebates provided to payers and Pharmacy Benefit Managers (PBMs). In fact, the discounts provided through the 340B program only increase if the prices of drugs increase. The higher the price of the drug, the higher the discount provided to covered entities. Nearly one-third of the total 340B discount is due to a penalty imposed on drug manufacturers for raising the price of drugs above the rate of inflation. Between 2014 and 2015, retail prices for 268 brand-name prescription drugs increased by an average of 15.5 percent; 130 times the rate of general inflation (0.1 percent).[3] If drug prices were not above the inflation rate, drug manufacturers would not have to provide higher 340B discounts. Therefore, the 340B program cannot be blamed for the increase of drug prices.

While HHS should strive to reduce patients' out-of-pocket costs for drugs and services, lowering the reimbursement of drugs will not achieve that objective. It would only make health care providers responsible for a greater portion of the cost, leaving 340B facilities with lower margins. Similarly, any narrowing of 340B eligibility to a smaller set of qualifying institutions will *not* lower drug prices. It will simply transfer the corresponding share of government payment for drugs from the hospital or the clinic to the drug manufacturer. At a time when drug prices are expected to continue increasing, the 340B program is essential to help hospitals compensate for the increased costs and afford drugs that would otherwise be difficult or impossible to purchase. Because the 340B savings are used to provide broader services and increased access to care, any payment reductions would impact patients and their access to treatment.

Scrutiny Over the 340B Program for Hospitals

[2] Dobson DaVanzo & Associates. Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers.
[3] W. Schondelmeyer and L. Purvis, Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2006 to 2015.

The Blueprint states that the President's budget "proposes reforms to improve 340B program integrity and ensure that the benefits derived from participation in the program are used to benefit patients, especially low-income and uninsured populations."

While there are improvements that can be made to the program, we do not believe its integrity should be in question. Covered entities that participate in the 340B program face strict requirements, routine audits and complex billing structures to ensure compliance. While we support efforts to ensure the integrity of the program, we recommend that HHS adopt a balanced approach. Drug manufacturers do not face the same scrutiny as hospitals, despite some manufacturers being found to charge hospitals more than the mandated 340B ceiling price for drugs. A report by the Office of Inspector General (OIG) found that in June 2005, 14 percent of all drugs purchased by 340B providers were over the mandated ceiling price, totaling an estimated $3.9 million in overcharges for that month alone.[4] In response to these findings, Congress directed HRSA to impose civil monetary penalties on drug manufacturers who knowingly and intentionally overcharged hospitals for 340B drugs.[5] Despite this mandate, HRSA has delayed a final rule to impose such civil monetary penalties five times.[6] **AHPA recommends that the Agency finalize the rule and make drug manufacturers accountable for their participation in the 340B program.** We also would like to remind the Agency that it is drug manufacturers who set drug prices, not hospitals. Therefore, we believe that efforts to curtail drug prices should not focus solely on 340B hospitals.

The Growth of the 340B Program

The Blueprint argues that the 340B program has grown significantly since 1992. One of the primary reasons that the number of eligible entities has grown is due to steps taken by Congress and HHS. The Affordable Care Act (ACA) increased the number of 340B sites eligible to participate in the program. It extended participation to Critical Access Hospitals, Sole Community Hospitals, Rural Referral Centers, Free-Standing Children's Hospitals and Free-Standing Cancer Hospitals. This significantly contributed to the 340B program's growth and was aligned with the program's original intent.

[4] Office of Inspector General. Deficiencies in the Oversight of the 340B Drug Pricing Program.
[5] Health Resources and Services Administration. Section 340B of Public Health Service Act.
[6] Health Resources and Services Administration. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation.

Changes made by HRSA to the way 340B covered entities are registered have also contributed to the perceived growth of the program. In 2014, HRSA changed how covered entities report the sites participating in the program. All clinics, services or departments located off-site of the 340B hospital, regardless of whether they exist in the same building, were required to register with the Office of Price Administration (OPA) as 340B child sites. Even though there were no changes to the physical locations that were participating, the number of sites reported grew as a result. This has given the appearance that the 340B program has grown exponentially. However, many of the "new" 340B entities were child sites that had been in the program for years before being required to submit separate registrations.

Questions Posed by HHS

Below are AHPA's responses to certain questions posed by HHS in the Blueprint. These questions relate not only to the 340B program but also to lowering drug prices overall.

Does the Group Purchasing Organization (GPO) exclusion, the establishment of the Prime Vendor Program and the current inventory models for tracking 340B drugs increase or decrease prices?

AHPA believes that the GPO exclusion contributes to increased drug prices and recommends that HRSA rescind Policy Release 2013-1. Policy Release 2013-1 forbids 340B hospitals from making initial purchases through a GPO account. This increases the costs of drugs for 340B hospitals because it requires hospitals to purchase initial inventories at the typically higher-priced Wholesale Acquisition Cost (WAC). Complying with the GPO exclusion also requires hospitals to maintain three inventories instead of two. These three inventories consist of 1) a 340B inventory for drugs that qualify as covered Outpatient drugs and are dispensed or administered to 340B-eligible patients; 2) a GPO inventory for Inpatient drugs or drugs that do not otherwise qualify as covered Outpatient drugs; and 3) a non-GPO, non-340B inventory for initial purchases and for when a covered Outpatient drug cannot be replenished with a 340B drug. This three-inventory system is highly complex and leads to many unintentional errors that result in significant repayments to manufacturers. Since the GPO exclusion, AHPA'S 340B hospitals have experienced a significant increase in regulatory compliance costs.

Would changing the definition of "patient" or changing the requirements governing covered entities contracting with pharmacies or registering off-site outpatient facilities (i.e. child sites) help refocus the program towards its intended purpose?

AHPA supports codifying the regulations surrounding the 340B program to refocus the program towards the original intent as iterated above. AHPA supports the Stretching Entity Resources for Vulnerable (SERV) Communities Act introduced by Congresswoman Doris Matsui (D-CA) and its proposal to clarify the program intent and definition of patient.

What benefits would accrue to Medicare and Medicaid beneficiaries by allowing manufacturers to exclude from statutory price reporting programs' discounts, rebates or price guarantees included in value-based arrangements? How would excluding these approaches from Average Manufacturer Price (AMP) and Best Price (BP) calculations impact the Medicaid Drug Rebate program and supplemental rebate revenue? How would these exclusions affect Average Sales Price (ASP) and 340B Ceiling Prices?

Changes to the calculations of the AMP and the BP will not have a strong effect on rising prices because they would not address the underlying issue of transparency. Manufacturers currently set the price for 340B drugs and there is no transparency around what the price should be. Since 2010, HRSA has been required to post online the drug prices available to 340B providers but has yet to do that because of the delay of the civil monetary penalty final rule. To achieve effective price transparency and curtail drug costs, AHPA supports requiring manufacturers to report 340B ceiling prices.

HRSA estimates that covered entities saved approximately $6 billion on approximately $12 billion in discounted purchases in Calendar Year (CY) 2015 by participating in the 340B program. It is estimated that discounted drug purchases made by covered entities under the 340B program totaled more than $16 billion in 2016 – a more than 30 percent increase in 340B program purchases in just one year. How has the growth of the 340B drug discount program affected list prices?
Has the growth caused cross-subsidization by increasing list prices applicable in the commercial sector? What impact has this had on insurers and payers, including Part D plans?

As explained earlier, the 340B program does *not* affect a drug's list price. The size of the 340B discount is calculated based on the increase of the drug price by the manufacturer. The discounted price available to 340B purchasers is based on a fixed base discount of 23.1 percent for brand name drugs. An additional discount is triggered *if* the manufacturer increases the drug price greater than the rate of inflation. This means that the greater the price of a drug, the greater the discount that 340B covered entities receive. Thus, the savings from the program are an effect of the increasing prices, not the cause of them.

What are potential policy approaches for applying some manufacturer rebates and all pharmacy price concessions to the price of a drug at the point of sale?

There are various challenges that impede the ability of hospitals to bill at the point of sale for drugs. To give hospitals access to the price of a drug at the time it is dispensed, massive health industry billing and technological changes would need to occur in collaboration with drug manufacturers. Additionally, rebates are currently structured to come *after* a drug is dispensed and during an incremental timeframe (i.e., annually, bi-annually or quarterly) based on drug volumes and contracting negotiations. Therefore, for this policy to be adopted, HHS would have to first address the current technological challenges impeding the application of manufacturer's rebates at the point of sale.

Medicare payment rules pay for prescription drugs differently when provided during inpatient care or administered by an outpatient physician. Do the differences between Medicare's Part A and Part B drug payment policies create affordability and access challenges for beneficiaries?

The differences between Medicare Part A and Medicare Part B do create affordability and access challenges for beneficiaries. However, the cost of services provided under Medicare Part A and Medicare Part B differ due to regulatory requirements and compliance costs that make the care provided in one setting more expensive than the other. To equalize payments, Medicare would have to align the regulatory requirements of both settings or merge Medicare Part A and Part B as it was once proposed by the Hospital Improvements for Payment Act (HIP) of 2014.[7] Otherwise, payment reductions would unfairly penalize hospitals and Hospital Outpatient Provider-Based Departments (HOPDs). Additionally, adopting a site-neutral payment policy would have no effect on drug pricing because this would only reduce reimbursement and not lower list prices.

While site neutrality could be beneficial to the patient, it overlooks the fact that providing patient care in a hospital or HOPD is more expensive than providing care in a physician office. The regulations required for administering drugs in a hospital or HOPD are much more rigorous than physician practices. Hospitals and HOPDs are required to have a larger team of trained doctors, nurses and pharmacists that monitor patients and are better equipped for handling adverse reactions. They are also required to comply

[7] House Ways and Means Committee. Brady Unveils Discussion Draft to Improve Hospital Issues in the Medicare System.

with United States Pharmacopeia (USP) 797 regulations, which are costly requirements assuring that the preparation of a drug is safe and clean. While physician offices are not always required to comply with these regulations, most state boards of pharmacy have adopted the USP standard for hospitals.

Are the current mechanisms for identifying and preventing duplicate discounts effective? What additional oversight or claims standards are necessary to prevent duplicate discounts in Medicaid and other programs?

The Medicaid Exclusion File (MEF) that is currently maintained by HRSA helps identify providers who have chosen to dispense 340B drugs to Medicaid patients in the fee-for-service program. The MEF is used to prevent duplicate discounts because it allows states to identify and exclude 340B claims when collecting Medicaid rebates from manufacturers. However, not all states use the MEF or have methods to correctly identify 340B claims. Different states use different methods for tracking 340B drug claims, which results in numerous complex regulations that covered entities must comply with. This lack of a uniform requirement can generate confusion among 340B participants and increase the possibility of duplicate discounts.

To avoid duplicate discounts, AHPA recommends that HHS create a nationwide standard for all covered entities and state Medicaid agencies to follow. This could be done by requiring that all states use the MEF. Standardizing the process for all states to track 340B discounts would help reduce the prevalence of errors and the number of duplicative discounts that occur.

Conclusion

AHPA welcomes the opportunity to further discuss any of the recommendations provided above. If you have any questions or would like further information, please do not hesitate to contact Julie Zaiback-Aldinger, Director of Public Policy and Community Benefit, at Julie.Zaiback@AHSS.org.

Sincerely,

Carlyle Walton
President
Adventist Health Policy Association