



A Passionate Voice for Compassionate Care

July 16, 2018

The Honorable Alex Azar
Secretary of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Re: RIN 0991-ZA49: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs: Request for Information

Dear Mr. Secretary:

The Catholic Health Association of the United States (CHA), the national leadership organization of the Catholic health ministry, representing more than 2,000 Catholic health care sponsors, systems, hospitals, long-term care facilities and related organization across the continuum of care, is pleased to offer comments on the referenced Request for Information (RFI).

The rising cost of pharmaceuticals is a serious obstacle for millions of Americans, especially those with low incomes, chronic conditions or catastrophic health diagnoses. We agree with the Administration that it is imperative to find ways to improve health outcomes while lowering out-of-pockets costs and overall healthcare costs, and we appreciate your reaching out to patients, providers, experts, other stakeholders and ordinary Americans for help in shaping future policy directions. However, the RFI mistakenly includes questions concerning the 340B drug discount program as it does not contribute to the problem of increasing drug prices. Nonetheless, we will take this opportunity to address some of the policies raised in the RFI.

Section 340B of the Public Health Service Act requires pharmaceutical manufacturers that participate in the Medicaid program to provide covered outpatient drugs at a discounted rate to safety net and other health care facilities serving low-income, vulnerable communities or remote rural areas. The significant pharmacy discounts available under the program allow hospitals to continue to provide and expand services that otherwise would not be available to these populations.

Congress created the program as a response to the high pharmaceutical costs faced by safety net hospitals. The intent was “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” Only hospitals that provide a



A Passionate Voice for Compassionate Care

significant level of care to low-income patients or serve rural communities are eligible to be in the 340B program. In 2015 340B hospitals of all types provided \$23.8 billion in uncompensated care¹ and \$51.7 billion in total benefits to their communities.² 340B DSH hospitals account for only 38 percent of all Medicare acute care hospitals but they provide nearly 60 percent of all uncompensated care, and are much more likely than non-340B hospitals to offer vital health care services that are often unreimbursed.

The savings from the 340B program allow safety net and rural hospitals to serve their patients and communities in many ways, according to local need. Many Catholic health ministry hospitals rely on 340B savings to, for example, run free and low-cost clinics; to provide infusion and other services in remote or low-income areas; to offer generous financial aid policies as well as programs that provide low-cost or free prescriptions; to maintain critical services that operate at a loss; and to support community benefit programs meeting the identified needs of their service areas. The 340B program plays a crucial role in providing access to health care in the communities served by Catholic health care.

The 340B Program Does Not Affect List Prices

The RFI references the growth of the 340B program and asks how that may have affected list prices. The 340B program is not driving drug prices. While the program has grown in recent years, it remains a relatively small program. The outpatient drugs purchased through the program represent a small portion of the overall market. In 2015, 340B drugs constituted just 2.8% of the \$457 billion in total annual drug purchases. The discounts realized by hospitals through the program totaled \$6 billion in 2015, which has been estimated to have reduced manufacturers total revenue by about 1.9%.³ It is unlikely that such a small program plays a role in manufacturers' raising list prices. Furthermore, there is no evidence manufacturers would react to any reduction in the 340B discount to hospitals by voluntarily lowering list prices rather than keeping those amounts or passing them on to shareholders. On the other hand, policy changes to restrict the availability of 340B discounts to hospitals would have harmful repercussions for the individual and communities that rely on services subsidized by 340B savings.

It is also important to acknowledge that the factors that have contributed to the program's growth. Congress expressed its intent to make the discounts available to additional vulnerable communities in 2010 when it expanded the types of hospitals eligible for the program to include critical access hospitals, rural referral hospitals, sole community hospitals, children's hospitals

¹ AHA 2015 Annual Survey Data

² AHA 340B Community Benefit Analysis, March 2018, accessed at <https://www.aha.org/system/files/2018-03/340b-community-benefit-analysis.pdf>

³ Coukell AJ, Dickson S. Reforming the 340B Drug Pricing Program Tradeoffs Between Hospital and Manufacturer Revenues. *JAMA Intern Med.* Published online May 21, 2018.



A Passionate Voice for Compassionate Care

and free-standing cancer hospitals. Manufacturer increases in the cost of outpatient drugs and the shift in the locus of care from inpatient to outpatient as health care delivery evolves have also contributed to growth in the 340B program.

Group Purchasing Organization (GPO) Exclusion

The 340B statute excludes from eligibility hospitals that purchase “covered outpatient drugs” from GPOs. HRSA’s long standing interpretation of the GPO exclusion allowed hospitals to purchase outpatient drugs initially through a GPO and replenish their inventories with a GPO or 340B drug based on patient eligibility, that is, whether the drug as prescribed was in fact a covered outpatient drug. In 2013 HRSA issued new policy guidance, Policy Release 2013-1, ending the ability of disproportionate share, cancer and children’s hospitals in most situations from using GPOs to purchase drugs initially. Hospitals could now only initially purchase outpatient drugs at a non-GPO, non-340B price.

The change requires hospitals to maintain three inventories: 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; and 3) a non-GPO, non-340B inventory for initial purchases and when a “covered outpatient drug” can’t be replenished with a 340B drug.

This system imposes unnecessary operating burdens for hospitals which must devote significant labor and software resources to tracking the inventories. It increases the costs hospitals pay for drugs when they must purchase non-340B, non-GPO drugs. It also subjects hospitals to severe sanctions for even isolated or inadvertent violations. Use of a single GPO drug on a hospital outpatient, even if unintended, can result in termination from the program or imposition of significant penalties.

The statute itself does not compel this approach. A drug only becomes a “covered outpatient drug” once it is furnished to an eligible patient and billed to a payer. Before that, it is simply a drug with no inpatient or outpatient status. Moreover, a drug’s purchase price typically is not final until after the manufacturer has settled with the wholesaler through the chargeback process, which can take days or weeks to complete, making HRSA’s initial purchase an illusory concept. We urge HHS to reevaluate the appropriateness of Policy 2013-1 and consider rescinding it and returning to its prior policy. At the very least Policy 2013-1 should be modified to reduce the administrative and regulatory burden on hospitals and to provide for less draconian sanctions when unintended or isolated violations occur.

Program Eligibility: Definition of Patient

The RFI seeks comment on whether there is a need to change the definition of patient to “refocus” the program on its intended purposes.



A Passionate Voice for Compassionate Care

Identifying patients of a covered entity eligible to receive 340B drugs is of course an essential element of the program. CHA believes the current definition is appropriate and aligned with the program's intent. It is based on the relationship between the patient and the 340B hospital and includes patients who receive 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. We strongly urge against changing the definition in a way that would limit the number of patients eligible to receive 340B drugs and thus reduce the volume of drugs eligible for 340B drug discount pricing. Doing so would deprive 340B hospitals of resources needed to continue to serve vulnerable patients in their communities.

Duplicate Discounts

Federal law provides that manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Our members are committed to preventing duplicate discounts and spend a great deal of time and effort to ensure that duplicate discounts do not occur. One difficulty they face is the fact that the Medicaid program is in fact 50 different state programs. States have a wide variety of mechanisms to achieve compliance, with little uniformity among them. This is a particular problem for health systems operating in multiple states. Another significant challenge is preventing duplicate discounts with respect to Medicaid managed care organization (MCO) patients. The burden for preventing duplicate discounts has generally been placed on covered entities. HHS, HRSA and CMS should work with stakeholders to develop guidance that reasonably shares responsibility for compliance fairly among covered entities, manufacturers and state Medicaid programs and MCOs.

In closing, thank you for the opportunity to share these comments on the RFI. We look forward to working with you to ensure that the 340B program will continue to provide needed resources to safety net hospitals and the low-income and rural communities they serve. If you have any questions about these comments or need more information, please do not hesitate to contact me or Kathy Curran, Senior Director Public Policy, at 202-721-6300.

Sincerely,

A handwritten signature in black ink that reads "Michael Rodgers". The signature is written in a cursive, flowing style.

Michael Rodgers
Senior Vice President
Public Policy and Advocacy