September 27, 2017

The Honorable Greg Walden Chairman United States House of Representatives Energy and Commerce Committee 2125 Rayburn House Office Building Washington, DC 20515 The Honorable Joe Barton Vice Chairman United States House of Representatives Energy and Commerce Committee 2125 Rayburn House Office Building Washington, DC 20515

Re: 340B Drug Discount Program

Dear Chairman Walden and Vice Chairman Barton:

On behalf of the undersigned organizations, and the millions of patients we serve, we are contacting you today regarding the 340B Drug Discount Program (the program). As the program has grown and evolved, it is critical to understand if patients are still at the center of the policy—not only driving cost savings for covered entities but truly benefiting from reduced drug prices and implementation of services that are critical to serving their comprehensive medical, social, emotional, and support needs. The patient advocacy community stands ready to work with Congress to bring the patient voice to discussions about the future of 340B program policy. Below, we outline several program areas we believe could be improved upon to better serve patients.

Patient Benefits

Neither the 340B statute, nor HRSA guidance, dictate how cost savings from the program are utilized by covered entities. This program was created to allow certain safety net providers to obtain discounted prices on covered outpatient drugs in order to help these entities stretch their scarce federal resources to meet the needs of vulnerable patient populations. Yet the government does not track how the cost savings are implemented. Some entities have been found to use savings to expand the number of patients served, such as federally qualified health centers, who may be required to use the revenue in ways consistent with grant requirements. Other entities may also use savings to invest in capital, cover administrative costs, or for any other purpose. Guidance is needed regarding the use of 340B cost savings. Although not a current requirement, we advocate that covered entities prove that these savings are directed back into patient care and support services.

Patient Support

In a 2016 Cancer Support Community study on access to care, it was found that patients surveyed felt that although they needed specific services, they were not able to receive the following: general support services (45%), treatment for side effects (38.9%), eating and nutrition counseling (38.3%), financial counseling (28.9%), and mental health counseling (26.2%). Additionally, 71% of respondents indicated that they did not receive any social and emotional support services as part of their cancer care. Across all health insurance types, individuals identified availability, coverage, and high cost as the top reasons that they did not receive such services. These are precisely the types of services that should be supported by cost savings generated by the program. Guidance is needed to define what types of services

(including psychosocial support services) covered entities should fund through program cost savings.

Patient Costs

If covered entities are saving money through the program, it is imperative that those cost savings also be realized by all patients. Covered entities are permitted to use discounted 340B drugs for all individuals who meet the current definition of "patient," not only those patients who are deemed low income, uninsured, or underinsured. As the Office of the Inspector General (OIG) (2017) reports, some covered entities take steps to ensure that 340B discounted prices are passed on to uninsured patients when they fill prescriptions at contract pharmacies (which are not a part of the entity and are allowable by the program) (Bliss, 2017). However, the OIG also found that this is not common practice with every covered entity and there are instances when uninsured patients pay full price for drugs filled at contract pharmacies. Guidance is needed regarding how the program applies to uninsured patients. We advocate that uninsured patients at 340B entities also benefit from the program cost savings and are not charged full price for their medications.

Patient Access

The number of hospitals enrolled in the program has jumped from 583 in 2005 to 1,679 in 2014 (Conti & Bach, 2014). Stakeholders have questioned whether the 340B expansion underlies the "trend toward consolidation and affiliations between community-based oncology practices and 340B eligible hospitals" as well as a trend towards more expensive care (Conti & Bach, 2014. Such vertical integration has the potential to limit patient choice, reduce the quality of care, and increase prices (Alpert, His, & Jacobson, 2017). It is important for patients to be able to access and afford health care services in their community of choice. More information is needed regarding the role of the program in hospital consolidation and affiliation, the preservation of community practice, and the impact on access, cost, and quality to determine if the program is undermining patient goals, preferences, and needs.

Conclusion

In conclusion, we understand the original intent of the 340B Drug Discount Program and applaud efforts to expand health care access to underserved populations, particularly those patients living in poverty. However, it is unclear if the original intent of the program has been realized. We encourage the following changes to, or guidance to clarify, the program: 1) oversight to guarantee that patients benefit from program cost savings; 2) guidance to outline what types of patient care and support services program cost savings can fund; 3) transparency requirements for entities to disclose how cost savings are being used to benefit patients; 4) guidance regarding how the program applies uniformly to all patients, including those who are uninsured; and 5) quality standards and oversight to ensure that the program is running effectively and benefiting patients. The patient *must* be at the center of this policy and we welcome the opportunity to work with Congress to improve the program to ensure that this occurs.

Sincerely,

Association of Oncology Social Work Cancer Support Community Global Healthy Living Foundation Leukemia and Lymphoma Society Living Beyond Breast Cancer Lung Cancer Alliance Lungevity Foundation Lupus Foundation of America Oncology Nursing Society Prevent Cancer Foundation

References

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