ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY

2318 Mill Road, Suite 800
Alexandria, VA 22314
T: 571.483.1300
F: 571.366.9530
www.asco.org

July 11, 2018

The Honorable Greg Walden
Chairman
Energy & Commerce Committee
U.S House of Representatives
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Energy & Commerce Committee
U.S House of Representatives
Washington, DC 20515

The Honorable Michael Burgess, MD
Chairman
Energy & Commerce Subcommittee on Health
U.S. House of Representatives
Washington, DC 20515

The Honorable Gene Green
Ranking Member
Energy & Commerce Subcommittee on Health
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Walden and Ranking Member Pallone, Chairman Burgess and Ranking Member Green,

The American Society of Clinical Oncology (ASCO) applauds the Committee's examination of the 340B Drug Pricing Program (340B program) in today's hearing, "Opportunities to Improve the 340B Drug Pricing Program." As the 340B Drug Pricing program (340B program) continues to grow in size so does its impact on health care accessibility and quality. We appreciate the Committee's continued efforts to ensure the program addresses the needs of underserved patients, particularly their ability to access cancer therapy. In January, ASCO responded to this Committee's thoughtful report reviewing the program.

ASCO represents nearly 45,000 physicians and other health care professionals specializing in cancer prevention, diagnosis, and treatment who provide cancer care both within and outside 340B-covered entities. In 2014, ASCO published its "Policy Statement on the 340B Drug Pricing Program" in the *Journal of Oncology Practice*,[i] which includes recommendation for reforming the 340B Program.

ASCO supports increased transparency, including an accounting of covered entities' 340B savings and the percentage of 340B savings used directly to care for underinsured patients and patients living on low-incomes.

In past letters to the Centers for Medicare and Medicaid Services (CMS) and to the Committee, ASCO recommended the Health Resources and Services Administration (HRSA) collect an annual comprehensive accounting of the amount of 340B savings covered entities receive under the 340B program and the percentage of those savings that are reinvested into caring for the uninsured, underinsured, and Medicaid patients. Such transparency is necessary to ensure the program remains true to its original intent. ASCO supports the transparency elements of several of the proposals under consideration by the subcommittee today, including provisions of *H.R. 4710*, the *340B Pause Act*, and *H.R. 5598, the 340B Optimization Act,* and the discussion draft to amend the Public Health Service Act (PHSA) which would require reports by covered entities to further the goal of transparency.

ASCO supports greater authority, resources, and staff for HRSA to conduct the increased oversight and enforcement needed for the 340B program.

While HRSA currently conducts audits of 340B covered entities, these audits are limited in scope. HRSA maintains a limited regulatory and enforcement authority to address compliance in the 340B program, however the scope and depth of that authority is not sufficient. ASCO applauds the Committee for considering measures to strengthen the oversight authority and resources of the agency.

ASCO urges Congress to discontinue the use of the Disproportionate Share Hospital (DSH) adjustment as a determining measure for program eligibility and urges Congress to create a metric that appropriately measures levels of charity care for program eligibility.

While ASCO recognizes the intent of legislation such as the *Protecting Safety-Net 340B Hospitals Act* to ensure the program focuses on providing care in those systems where need is the greatest, we do not believe DSH is the appropriate formula to calculate that need. ASCO calls on the Committee to work with ASCO and other stakeholders to identify a formula that would more appropriately recognize levels of charity care across the entire cancer care delivery system. DSH determinations do not capture all services to outpatient populations that are underserved or medically indigent.

New 340B hospital eligibility measures are needed to better link program eligibility with the program's intent. Policymakers should focus on metrics that align program eligibility with the care provided by the institution to indigent and underserved individuals. Doing so will better position the program to serve the patient populations originally intended to benefit. Alternative eligibility measures may be calculated by analyzing the amount of charity care provided by a hospital in the outpatient setting or another appropriate metric. However, any potential metrics must be designed to promote participation by hospitals of all sizes, standardized across all hospitals to ensure that eligibility is based on a single set of parameters applied in uniform fashion, and verifiable to ensure that program integrity is protected. ASCO is prepared and ready to assist Congress and the Administration in developing and implementing policies to better reflect the original intent of the 340B program in this area.

ASCO urges Congress to keep the impact of the 340B program on cancer patients and access to cancer care at the forefront moving forward with reform.

ASCO agrees that the 340B program needs reform. However, significant payment reductions like the one most recently implemented by HHS do not address the fundamental flaws in the program. If enacted in

conjunction with other program reforms, we support H.R. 4392 to nullify the 22 percent reduction in 340B reimbursement that took effect earlier this year.

ASCO is concerned that the cut could harm the very facilities that are truly satisfying the spirit and intent of the program. ASCO urges policymakers to focus on meeting the original intent of 340B to provide resources and incentives for the delivery of high-quality care for uninsured, underinsured, and low-income patients.

Because drug therapies are a fundamental part of cancer treatment, the 340B program has had a strong influence on the cancer care delivery system by encouraging consolidation. Practice closures and acquisitions have had a major impact on access to cancer care in communities across the country. For the same reasons, we urge the Committee to consider the challenges physician-owned oncology practices face when providing care to vulnerable populations in rural, frontier, and other small communities experiencing access issues.

We further call on Congress to consider the impact the 340B Drug Pricing program puts on physician oncology practices and to work with HRSA to establish 340B eligibility for all oncology practices demonstrating a commitment to serving low-income and underserved patients.

Community oncology practices are vital outlets for patient access to high-quality and cost-efficient oncology services for cancer patients from all walks of life. These practices regularly engage in the provision of care to indigent, underserved and uninsured individuals at a financial loss, yet do so without the benefit of 340B discounts enjoyed by oncology providers in other settings of care. Community based oncology practices form the backbone of cancer care in many rural and underserved areas by serving as the sole point of access for oncology services.

ASCO supports expanding eligibility to the 340B program for community oncology practices with a demonstrated commitment to serving uninsured, underinsured and indigent patients to promote increased access for these individuals. ASCO's working group is developing a mechanism to provide a pathway to eligibility for community oncology practices that is based on the portion of care a practice provides to uninsured, underinsured and indigent individuals relative to the levels of other community practices. Minimizing regulatory burdens for clinical oncology practices of all sizes to demonstrate 340B eligibility is crucial to meeting the program's original intent. Any eligibility criteria for community-based practice eligibility should be designed to facilitate participation by practices of all sizes, defined based on standardized data that are unique to community practice, and verifiable to promote program integrity.

ASCO thanks the Committee for its commitment to improving the 340B program. If you have questions about this or any issue affecting cancer care, feel free to reach out to Amanda Schwartz at amanda.schwartz@asco.org or 571-483-1647.

Sincerely,

Monica M. Bertagnolli, MD, FACS, FASCO
President, American Society of Clinical Oncology