Oncology Nursing Society
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October 29, 2020

RE: Request for Information on the 340B Drug Pricing Program

Submitted electronically 340B@help.senate.gov and 340B@mail.house.gov.

Dear Chairman Alexander and Ranking Member Walden:

The Oncology Nursing Society (ONS) writes in response to your request for information (RFI) related to the 340B Drug Pricing Program. Thank you for the opportunity to submit feedback and suggestions to ensure that this critical program serves vulnerable, low-income patients.

The 340B program guarantees access to deep discounts on outpatient drugs for safety net providers. Pharmaceutical companies who wish to participate in Medicaid must offer 340B discounts to covered entities. The program is administered by the Health Resources and Services Administration (HRSA). As the RFI highlights, 340B has experienced immense growth in the last decade, both in the number of covered entities and the number of contract pharmacies.

The statute specifies categories of eligible entities, and it is indisputable that 340B is a lifeline for many of these providers. Most of the covered entities only serve very vulnerable populations (e.g., black lung and tuberculosis clinics, Ryan White Care Act grantees, AIDS drug assistance programs, Native Hawaiian health centers, Urban Indian clinics, and Federally Qualified Health Centers). Others may serve limited geographic areas (e.g., rural hospitals) or limited disease states (e.g., freestanding cancer hospitals). Others, such as disproportionate share hospitals, serve high numbers of low-income, uninsured, or underinsured patients.

One of the main areas of disagreement and confusion among stakeholders is whether certain *patients* should be guaranteed access to 340B pricing. The statute is silent on this; rather, it only guarantees access to 340B pricing for the covered *entity* and prohibits transfer or resale of drugs purchased pursuant to 340B to any person who is not a patient of the covered entity. Whether the covered entities choose to pass these discounts through to their patients is entirely within their discretion. A Government Accountability Office survey found that a majority of surveyed entities do, but some do not. *If passing 340B discounts through to certain patient populations is a goal of the program, Congress should specify this in the statute. Given the financial toxicity of cancer, ONS supports any policy that reduces the out-of-pocket cost of cancer care – including medicines – for patients.*

An indisputable fact about the 340B program is that it has gotten very large. A recent *Health Affairs* article noted that, in 2015, "the Department of Health and Human Services (HHS) reported that discounted 340B sales were $12 billion and 340B discounts were worth $6 billion, meaning that without discounts, the drugs

would have accounted for $18 billion in sales."[1] Responsible stewardship of a program this size is critical, but it is our understanding that, besides registration requirements, there are no reporting requirements for covered entities. *If Congress wishes to ensure that 340B discounts are passed through to patients, a first step might be to require additional information and data-reporting from covered entities with regard to their 340B purchases, pharmacy relationships, and 340B dispensing.*

Additionally, there is an overall trend towards consolidation among oncology providers, which some stakeholders believe is accelerated in part by the 340B program. According to the Community Oncology Alliance, between 2008 and 2018, 658 independent oncology clinics were acquired by or entered into contracts with hospitals and 423 clinics closed, with Florida, Michigan, and Texas experiencing the highest numbers of closures.[2] These consolidations and closures are the result of a combination of factors, including Medicare reimbursement cuts due to sequestration and the inability to compete with 340B discounts. *Once Congress gathers more data on the 340B program, it should examine the relationship between 340B and consolidation among and closures of independent, community-based oncology providers.*

ONS appreciates the opportunity to comment on these important issues, and we look forward to a continuing dialogue. If you have any questions about our comments, please contact Alec Stone, Public Affairs Director, at astone@ons.org.

Sincerely,

The Oncology Nursing Society

About ONS

The Oncology Nursing Society (ONS) is a professional organization of over 39,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing. ONS members are a diverse group of professionals who represent a variety of professional roles, practice settings, and subspecialty practice areas. Oncology nurses are leaders in the healthcare arena, committed to continuous learning and leading the transformation of cancer care by advocating for high-quality care for people with cancer.

[1] "The Size of the 340B Program and Its Impact on Manufacturer Revenues" by Sean Dickson, Allan Coukell, and Ian Reynolds, *Health Affairs Blog* (Aug. 8, 2018).

[2] "What's driving cancer clinics to close? Cuts to 340B, Medicare Part B, oncologists say" Advisory Board Daily Briefing (May 4, 2018).