The 340B Drug Pricing Program
Community Oncology Alliance Position Statement

Community Oncology Alliance Position:
The Community Oncology Alliance (COA) believes that 340B Drug Pricing Program discounts should follow the patient, not be "awarded" to a hospital. Hospitals should only receive 340B discounts when treating underinsured, uninsured, and indigent patients. COA also believes any 340B drug discounts that serve to create profit centers for hospitals, which is outside the intent of the 340B program, should be eliminated. COA further believes transparency should exist through hospitals reporting revenues from the program, accountability should be established through set expectations regarding use of incremental revenue to serve vulnerable populations of patients, and compliance should be monitored through the statutory oversight authority of HRSA. COA strongly supports the more rigorous audit program now under consideration and recognizes HRSA will require appropriate funding and staffing to execute its mission to properly and, in a timely manner, audit 340B covered entities. Such transparency and accountability will restore the original intent of the valuable program.

Background:
A Well-intended Program Gone Awry
340B is a federal program that requires drug manufacturers to provide outpatient drugs at significantly reduced prices to eligible health care organizations that are supposed to treat high numbers of underinsured, uninsured and indigent patients. Eligible participants include non-profit hospitals, community health centers, Ryan White HIV/AIDS clinics, black lung clinics, and other designated facilities that treat underinsured, uninsured and indigent patients. The original concept of the 340B program was that by providing access to deeply discounted drugs (upwards of 50 percent), participants would be able to use savings to provide needed services and medication for the underinsured, uninsured and indigent patient populations they treat.

The 340B program was aimed at a very small subset of safety-net providers. According to a report by the Medicare Payment Advisory Commission (MedPAC) to Congress, 340B grew very slowly to include just 583 participants after its first 13 years of existence (1992 – 2005). Since then, however, 340B has exploded, with most of the growth being driven by hospitals.[1] By 2014, there were 2,140 hospitals participating in 340B, a 367 percent increase in just nine years after the Medicare Modernization Act (MMA). Today, approximately 45 percent of all acute care hospitals participate in the 340B program.[2]

The program has grown and changed over time and there has been insufficient reporting, monitoring, auditing, and oversight. Hospitals have used the 340B program for purposes never intended as an access to deeply discounted drugs. Because of their access to discounted drugs, irrespective of the volume of underinsured, uninsured and indigent patients served, hospitals are establishing outpatient cancer centers. The natural consequence of the powerful economic incentives surrounding the development of hospital-based cancer clinics is the consolidation of community cancer centers into hospital outpatient departments participating in the 340B program.

The growth of the 340B program has been a powerful driver to facilitate hospital consolidation. The Milliman report in 2016 demonstrated that from 2004-2014, the proportion of chemotherapy infusions delivered in the hospital outpatient setting nearly tripled, increasing from 15.8 percent to 45.9 percent for the Medicare population and 5.8 percent to 45.9 percent for the commercially insured population. This shift increases the cost of care as hospital outpatient departments are a more expensive site of service because of higher costs per treatment, per episode of care, and facility fees incurred for hospital outpatient treatment. On average, the cost of care is about double in the hospital outpatient department in comparison to a private community practice setting.[3] This shift in site of service has increased costs without meaningfully translating into improved care for vulnerable patients with cancer.

As consolidation progresses, patients, especially rural patients, must travel farther to access cancer care. There is a documented issue of increasingly diminished cancer care the farther patients live from their care provider. A recent study shows that an increased travel burden was associated with a decreased likelihood of receiving adjuvant chemotherapy, regardless of insurance status. Patients with nonprivate insurance who resided in low-density oncologist areas were less likely to receive adjuvant chemotherapy.[4] In rural areas still served by community-based oncology practices, 340B driven consolidation of such clinics into hospital outpatient departments can be devastating and limit access to local care. COA recognizes that rural oncology care and access to that care should not be put in jeopardy by 340B consolidation.

With program growth, there should be an increase in the provision of charity care to serve the country's most vulnerable patients with cancer. On average, that has not occurred. While there is likely variability between 340B qualifying entities providing care to vulnerable patients, on average, the differences in the number of low income and indigent patients treated by 340B qualifying hospitals and non-qualifying hospitals is minimal. As of 2015, there was only a 1 percent difference in the amount of uncompensated care provided by 340B qualifying hospitals in comparison to non-340B qualifying hospitals and participating hospitals were no more likely to offer low-profit services.[5]

The 340B drug discount aims to increase unreimbursed care to uninsured and low-income populations by reducing the price of drug-based care. While the program does increase the administration of physician-administered drugs, especially high-cost oncology drugs, patient out-of-pocket costs and uncompensated care provision [also] increases. On net, participation is not fully passed onto patients.[6] Further study results indicate specifically, participating in 340B, increases Medicare revenue by 20.57 percent and cost-sharing amounts billed to beneficiaries by 16.79 percent.[7]

Regulation of 340B

The Health Resources and Services Administration (HRSA) is the regulatory body that administers the 340B program. This agency does not have clear regulatory authority to enforce the goals of the program, nor is the agency staffed appropriately to conduct proper audits. The Office of the Inspector General's initial [review of audit] work, released in the early 2000s, found deficiencies in HRSA's oversight of the program. These deficiencies included inaccurate information regarding which providers were eligible for discounted prices and a lack of systematic monitoring to ensure that drug manufacturers were charging 340B providers the correct prices.[8]

HRSA was also granted new enforcement tools, including authority to conduct audits of both manufacturers and 340B providers and to impose civil monetary penalties for manufacturers that knowingly and intentionally overcharge 340B providers.[9] Some of HRSA's efforts to implement its new oversight authorities and to clarify program rules through regulations were either unsuccessful or remain unfinished, leaving too much of the 340B program without proper oversight.

The Government Accounting Office (GAO) reported that in 2017, HRSA audited 200, or 1.6 percent, of the 340B covered entities.[10] By 2018, this shockingly low number had barely improved. As of April 1, 2018, [HRSA] had completed 981 covered entity audits since it began auditing in 2012, which encompasses nearly 13,000 outpatient/off-site facilities and nearly 21,000 contract pharmacy locations. In FY 2018, HRSA [was] on track to conduct an additional 200 covered entity audits.

The findings of HRSA audits have varied. Some findings were minor, requiring basic corrections in the 340B database (e.g., contact or address information was incorrect). Other audits found diversion, either through ineligible providers or ineligible sites. For audits with findings of a possible duplicate discount violation, the covered entity is required to work with the state to clarify and resolve the issue.[11] HRSA has been working with Congress to establish language that would require 340B entities to participate in third party audits of their use of the 340B program. In such a program, audit results would be reported in the public domain. Presumably these audits would identify 340B program entities operating outside the parameters of the 340B program, as well as those operating within the letter of the program, but not within the spirit of 340B and therefore not achieving the intended benefits of 340B.

One of the most egregious practices that such audits will address is duplicative discounts, a process whereby manufacturers provide a discounted 340B price and a Medicaid drug rebate for the same drug. 42 U.S. Code § 256b prohibits manufacturers duplicative discounts. Covered entities participating in 340B must have mechanisms in place to prevent duplicate discounts.

The Medicaid Exclusion File (MEF) lists covered entities that have chosen to use 340B drugs for their Medicaid patients and to bill Medicaid for those drugs. The National Association of Medicaid Directors (NAMD) recommends that there be technical enhancements to the MFE to prevent any duplicative discounts within the 340B program. In 2016, the Centers for Medicare and Medicaid Services (CMS) notified all state Medicaid directors that states would be required to identify instances where duplicative discounts might occur as a result of overlaps between Medicaid and the 340B drug acquisition cost reductions. Currently, the HRSA audit system does not have the capacity to determine compliance with this requirement. Any further or future changes to the HRSA audit of 340B entities must provide for such capabilities.

As most cancer patients have been in a hospital at some point preceding or during their cancer diagnosis with cancer, the reconciliation process is not a meaningful way to determine if a patient is receiving treatment that is being applied to the 340B program. This has led to patients being encouraged to use the 340B designated facility for treatment instead of a community oncology clinic because of the economic incentives to that entity. This is one of the drivers of the current consolidation trend.

Summary:
The Community Oncology Alliance (COA) is committed to ensuring all patients with cancer have access to local, affordable care in a setting of their choosing. The 340B Drug Pricing Program (340B) has fueled significant consolidation of the nation's cancer care system, driving independent, community oncology practices to close or merge with hospital outpatient departments. This consolidation has reduced patient access and choice of treatment sites while also substantially increasing the cost of cancer care. COA is extremely concerned that the 340B program has been diverted from benefitting the country's most vulnerable patients and instead is benefitting hospitals and corporations.

HRSA will require appropriate funding and staffing to execute its mission to properly and, in a timely manner, audit 340B covered entities. Such transparency and accountability will restore the original intent of this valuable program.

Date:
Approved by the COA Board of Directors on September 16, 2019.

References:

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[10] *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, United States Government Accounting Office, Report to Congressional Requesters, June 2018, GAO-18-480.*
[11] *80 Fed. Reg. 52300 (August 28, 2015). qtd in Effective Administration of the 340B Drug Pricing Program, Capt. Krista M. Pedley, Testimony: Before Committee on Health, Education, Labor & Pensions, June 19, 2018.*