Background

The 340B drug discount program, as originally intended by Congress, provides a very valuable safety net for helping to ensure that patients in need — both uninsured and underinsured — receive medical treatment. However, the program has grown significantly, especially in terms of the number of qualifying non-profit hospitals, since 2005 when Medicare reimbursement for Part B drugs was lowered for hospital outpatient departments and physician-owned community cancer clinics. The 340B program has allowed qualifying hospitals to realize increased revenue by accessing 30-50% discounts on outpatient drugs.

Federally qualified community health centers, hemophilia treatment centers, and other community safety net providers are generally required to demonstrate that services are provided to needy or certain vulnerable populations, and that there is a reinvestment in those services. Those providers are specifically held to high standards of transparency and accountability. This is not the case with non-profit hospitals, where 340B eligibility is determined in part on their disproportionate share of Medicare and Medicaid inpatient days, which does not align with the 340B program that covers outpatient drugs related to care of needy individuals who are uninsured or underinsured.

There are many hospitals that abide by the intent of the 340B program and provide charity cancer care and other medical treatment to people without health insurance or without sufficient insurance; however, data suggests that those hospitals are in the minority.1 With relatively little oversight, as documented by government reports and investigations, such as a report by the Government Accountability Office2, the 340B program is being used in some cases by hospitals to acquire physician-owned community cancer clinics and to add to hospitals’ operating profits to fund buildings and facilities. This creates perverse incentives that can be detrimental to patient care and that can lead to increased costs for patients, Medicare, and insurers. Most fundamentally, a hospital’s participation in the 340B program does not guarantee that those individuals most in need are actually provided with cancer treatment and other types of medical care.

Position

COA’s position is that the 340B program is a very valuable safety net program but one that requires modification and oversight to ensure that program resources are more closely aligned with indigent patient (uninsured and underinsured) care. COA calls on the Department of Health and Human Services (HHS) — specifically, the Office of Pharmacy Affairs within the Health Resources and Services Administration (HRSA) of HHS — and Congress, given the limits of HRSA regulatory authority, to strengthen the 340B drug discount program by issuing regulations and/or passing legislation that accomplish the following:

- Revising the criteria and metrics for determining 340B eligibility for nonprofit hospitals to better align 340B discounts with delivery of indigent care and to ensure that 340B hospitals are true safety net facilities treating a documented disproportionate share of uninsured and underinsured patients. Eligibility based on the current disproportionate share hospital (DSH) metric is

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1 Unfilled Expectations: An Analysis of Charity Care Provided by 340B Hospitals, Alliance for 340B Integrity and Reform, March 2014.
inappropriate because the DSH metric is based largely on inpatient care whereas the 340B program covers outpatient drugs. The 340B eligibility formula must be based on a measure of uninsured and underinsured outpatient care.

- 340B eligibility for hospitals should be similar in transparency and accountability as eligibility requirements for community health centers and similar qualifying 340B entities. 340B hospitals should be required to provide financial reports on 340B savings and the percentage of those savings used to provide care to uninsured and underinsured patients.

- Ensuring that patient care is not compromised by 340B entities due to financial incentives from discounts on high cost cancer drugs.

- Clarifying specific program definitions, including eligible patient, covered entity, and outpatient department.

- Ensuring that HRSA has sufficient resources and funding to properly regulate and audit the 340B program, commensurate with the program’s growth.

COA also calls on all medical providers and organizations that want to protect the 340B program to engage in responsible, constructive dialogue about the 340B program. COA believes that the 340B program is more important than ever as a safety net, especially for cancer patients. If the program is not responsibly modified to align resources with delivery of indigent care, it will be those patients most in need who will be disadvantaged.

Information Supporting the Position of COA on the 340B Program

- The Medicare Modernization Act (MMA) in 2003 changed Medicare Part B drug reimbursement for the intended purpose of better aligning payments for drugs and services, especially for cancer care, with their respective underlying costs. Previously, Congress developed the payment system such that an overpayment for drugs (based on a set average wholesale price) covered unreimbursed services to outpatient hospital departments and physician-owned community cancer clinics, such as charity care, psychosocial support, Medicaid under-reimbursement, etc. Implementation of the MMA average sales price (ASP) in 2005, which significantly lowered Medicare drug reimbursement, was a major inflection point for the growth of the 340B program among hospitals. That is because it became apparent that DSH hospitals could qualify for the 340B program and realize discounts from 30-50% on the same outpatient drugs that were lowered in reimbursement by the MMA, with the effect of actually increasing revenue relative to cost through the 340B program.

- A recent study reported that 69% of 340B hospitals have charity care rates below the national average of 3.3% of all hospitals (including for-profit hospitals).\(^3\) The study also reports that 22% of the 340B hospitals provide 80% of the charity care provided by those hospitals, which given their reported size and percentage of total costs means that these hospitals provide a disproportionate high level of charity care.\(^4\) Clearly, some hospitals are living up to the intent of the 340B program and are true safety net facilities. Others, however, are not. Even though this study parallels similar findings about levels of charity care, the results have been attacked with broad statements, rather than with data. Every hospital living up to the intent of the 340B program should be very concerned that all 340B hospitals live up to the same standards and levels of true charity care.

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\(^3\) See supra, footnote 1.
\(^4\) Ibid
• With the implementation of the MMA, there has been regular ratcheting down of Medicare reimbursement by the Centers for Medicare & Medicaid Services (CMS). Additionally, the application of the sequester cut to cancer drug payments by CMS has put tremendous financial burden on community cancer clinics, which further threatens their survival. For many Medicare and Medicaid patients, treatment reimbursement to clinics is less than costs. Therefore, more of those patients are being referred to hospitals for treatment, especially those hospitals with 340B resources that are not available to community cancer clinics. Moreover, with the recent trend in insurance cost shifting to individuals, which will result in increasing numbers of cancer patients being underinsured, it is more important than ever that 340B resources are appropriately utilized for these at risk patients.

• In part, hospitals qualify for the 340B program based on their DSH percentage, which is in turn based on a formula of inpatient days covered by Medicare and Medicaid. However, 340B is a program covering outpatient drugs and intended for uninsured and underinsured outpatients. The 340B eligibility metric neither is aligned with underlying program intent nor is there any reporting requirement to ensure that program intent is being realized. This contrasts with community health clinics and similar providers that are held to specific standards of transparency and accountability to obtain and maintain 340B eligibility.

• The 340B program, which provides margins on cancer drugs as large as 100%, provide possible perverse financial incentives that can compromise patient care. Patient care, both in terms of quality and safety, must be ensured. Cases of compromised quality and safety include a 340B hospital directing patients to physically pick up their chemotherapy at a hospital’s 340B covered pharmacy and carrying those drugs (referred to as “brown bagging”) to their oncologist for administration. Another case involves a 340B hospital dictating that a patient’s chemotherapy regimen be split between two facilities so that the highly discounted brand drug is administered in a 340B eligible facility, while the lower cost and discounted generic drugs are administered in the facility yet to gain 340B eligibility.

• HRSA has a very small budget that has not been increased even slightly in line with the growth of the 340B program, especially the hospital portion of the program. The 340B program now accounts for 62% of current hospital outpatient drug spending and one-third of all hospitals are 340B eligible. Various investigative reports by government agencies have uncovered problems with the 340B program, which is due to lack of proper oversight attributed to budget constraints. There have long been definitional problems with various elements of the 340B program, which have not yet been clarified by HRSA.

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6 See *supra*, footnote 2.