October 2, 2020

Electronically submitted to: http://www.regulations.gov

The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1736-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals (CMS-1736-P)

Dear Administrator Verma:

On behalf of the Board of Directors of the Community Oncology Alliance (COA), we are submitting this comment letter to the Centers for Medicare & Medicaid Services (CMS) in response to the proposed rule Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals (Proposed Rule).

As you know, COA is an organization that is dedicated to advocating for the complex care and access needs of patients with cancer and the community oncology practices that serve them. COA is the only nonprofit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. COA’s mission is to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities where they live and work. Over the past 17 plus years, COA has built a strong national grassroots network of community oncology practices to advocate for public policies to support patients with cancer.

COA is specifically providing comments on CMS’ proposal in the rule to reduce the payment rate for drugs acquired under the 340B Drug Pricing Program (340B Program).

COA strongly supports the Proposed Rule changes to the 340B Program reimbursement and encourages CMS to consider a much broader and fundamental reform of the program to ensure that 340B discounts inure to the benefit of patients in need, rather than to hospitals.

COA appreciates CMS’ acknowledgment that 340B Program drug payment rates need to be addressed to better reflect the prices at which covered entity hospitals acquire these drugs. CMS proposes addressing this issue by reducing the payment rate for drugs acquired under the 340B...
Program to average sales price (ASP) minus 34.7 percent plus an add-on payment of six percent of the product’s ASP. We strongly agree that serious payment reforms are needed for the 340B Program, especially given the new insights into hospital acquisition costs obtained from the recent 340B hospital survey.

COA has long advocated for much-needed fundamental reforms to address a multitude of problems with the 340B Program, including ensuring that drug discounts under the program “follow the patient” as they are intended to, rather than create windfall profits for hospitals.

The 340B Program was intended to provide access to deeply discounted drugs for a small subset of safety-net providers so that these providers could use the savings to provide services to the underinsured, uninsured, and indigent patients that they served. What gets lost in all the 340B Program messaging “hype” from hospital systems and 340B Program advocates is that the 340B Program was created soon after Medicaid “best price” rebates were created. The “best price” formula stopped all voluntary drug discounts pharmaceutical manufacturers had traditionally provided because those discounts would become the “best price.” As a result, companies participating in the Medicaid program were required to provide section 340B discounts to a relatively small group of safety-net hospitals. These safety-net hospitals were intended to “stretch scarce resources” to help patients in need, who did not qualify for Medicaid and could not afford their prescription drugs.

COA strongly supports the 340B Program, which should offer a valuable safety-net for helping to ensure that low-income patients receive medical treatment. However, the program today has grown out of control and is abused as a predatory tool by bad actors in the hospital sector. Hospitals perversely manipulate and take advantage of the program to make substantial profits from oncology drugs and other expensive specialty medications purchased through the 340B Program and pressuring independent community oncology practices to sell out to the hospitals. This trend of consolidation shifts cancer care to the much more expensive hospital setting, raising costs for patients, Medicare, employers, and taxpayers.

The 340B Program today includes about 43,000 sites. Specifically, hospital participation in the program grew from a few hundred participating entities in 2005 to 2,140 hospitals in 2014, a 367 percent increase in just nine years. Today, approximately 45 percent of all acute care hospitals participate in the 340B Program.1 COVID-19 and the resulting economic downturn is projected to cause an influx of Medicaid lives, which in turn is projected to result in another 220 hospitals potentially gaining eligibility in the near future.2

As the 340B Program has continued to grow unchecked it has come to dominate and pervert the U.S. drug market as manufacturers are forced to account for more and more 340B discounts. A recent, independently produced white paper finds that 340B sales for both name brand and generic drugs are approximately 11 percent of the total U.S. pharmaceutical market, or $67.4B (sales volume dollarized using Wholesale Acquisition Cost). 26.9 percent of 340B Program dollar sales are for antineoplastics – drugs often used to treat cancer – which is, not coincidentally, the largest therapeutic area in the program.3

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2 Avalere analysis of Medicare Cost Reports Data, FY 2021 IPPS data, 340B database, FY2018-2020 IPPS Medicare DSH Supplemental Data Files, and Avalere’s proprietary enrollment model that estimates changes in insurance coverage due to the COVID pandemic
This program’s growth has not been accompanied by a proportionate increase in the provision of charity care to serve the program’s intended target population of low-income patients; as of 2015, there was only a one percent difference between the amount of uncompensated care provided by 340B qualifying hospitals and non-340B hospitals. As the program has grown, there has been insufficient reporting, monitoring, auditing, and oversight.

The 340B Program needs serious reform, beyond the payment rebalancing undertaken by CMS in the Proposed Rule. COA strongly believes that 340B discounts should follow the patient, insuring directly to the benefit of the patient, rather than hospitals that use these precious funds in any self-enriching manner they see fit. There is no accountability and transparency as to how 340B discounts are used by hospitals or if it actually lowers patient drug costs. The 340B Program has become a veritable printing press for hospitals to make unregulated profits. What we find unimaginable are the numerous press reports on 340B hospitals using strong-arm debt collection practices on their patients. 340B discounts should be made available to all qualifying patients in need, regardless of the site of care, rather than being entrusted to large, consolidating “profit-seeking” “nonprofit” health systems.

Any means for 340B discounts to be used to create perverse profit incentives for hospitals must be eliminated from the program. CMS’ proposal to reduce 340B drug payment rates is based on results from the Hospital Acquisition Cost Survey for the 340B-Acquired Specified Covered Drugs. As CMS notes in the Proposed Rule, the survey results reveal that the typical acquisition cost for 340B drugs for hospitals paid under the Outpatient Prospective Payment System (OPPS) is ASP minus 34.7 percent. Without accounting for outliers, the arithmetic mean discount from ASP is 66.3 percent, the median is 70.4 percent, and the geometric mean is 58.3 percent. Clearly, hospitals are receiving significant discounts through the 340B Program, yet these discounts are spirited away from directly helping patients in need afford the very same drugs that hospitals are profiting from. We find it perverse that hospitals are profiting from expensive cancer drugs while also claiming that the patients they serve can’t afford them.

Given the ongoing COVID-19 crisis, ensuring patients in need benefit directly from 340B drug discounts is more critical than ever, as millions of Americans have lost their jobs and insurance. Given the current “out of control” state of the 340B Program, and especially during the current public health emergency, COA believes that hospitals should be required to report revenues from the program in order to increase transparency, expectations should be set for hospitals to use revenue to serve vulnerable patient populations, and HRSA should use its authority to aggressively monitor and audit the program. Together, these steps can at least stem the abuses in the 340B Program and start moving it towards its originally intended function of serving low-income patients in need of affordable care, as well as end the harmful trend of oncology care consolidation. However, we reiterate that the 340B Program needs to be fundamentally changed so that 340B drug discounts help patients in need afford their medications.

The Trump administration’s recent executive order (EO) on 340B requires Federally Qualified Health Centers (FQHCs) to make insulins and injectable epinephrine available to low-income patients at the 340B price and ties FQHCs’ grant funding to compliance with this policy. While we support the spirit of the EO that aims to ensure low-income and underinsured patients benefit fully from 340B discounts, we believe that FQHCs and other government grantees should not be the targets for 340B reform. The EO does not

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4 Diversity of Participants in the 340B Drug Pricing Program for US Hospitals, Nikpay, S, Buntin, M, Conti, R, JAMA Intern Med, May 21, 2018
5 CY2021 OPPS Proposed Rule
address abuses of the program by hospitals and institutions that do not provide the same level of support to indigent patients or are subject to the same oversight requirements as the federal grantee entities.

As an alternative, COA hopes to see more comprehensive 340B Program reform that ensures low-income patients benefit from 340B drug discounts across all eligible drugs. Changes to the 340B Program should not be addressed at FQHCs, but rather at hospitals, which for the most part are the bad actors profiting from a program that has grossly mutated from the original congressional intent. We note that the federal grantees, and hospitals that use the 340B Program to directly benefit patients in need, are being harmed by those hospital systems that obscenely profit from abusing the program for the benefit of their institutions.

COA appreciates CMS’ attention to the issue of 340B drug payment rates and calls for additional policymakers’ attention to ensure the drug discounts truly benefit patients, as they were intended to when Congress created the program. We are more than willing to work with both the administration and Congress on these efforts and encourage you to please not hesitate to reach out to us with any questions.

Sincerely,

Michael Diaz, MD
President

Ted Okon
Executive Director