September 8, 2017

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-1678-P
P. O. Box 8013
Baltimore, MD  21244-8013

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (CMS-1678-P)

Dear Administrator Verma:

On behalf of the Board of Directors of the Community Oncology Alliance (COA), I am submitting this comment letter regarding Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (CMS-1678-P) (the “HOPPS Proposed Rule”).

The Community Oncology Alliance (“COA”) is a non-profit organization dedicated to advocating for community oncology practices and, most importantly, the patients they serve. COA is the only organization dedicated solely to independent community oncology where the majority of Americans with cancer are treated. The mission of COA is to ensure that cancer patients receive quality, affordable, and accessible cancer care in their own communities. For more than 15 years, COA has built a national grassroots network of community oncology practices to advocate for public policies that benefit cancer patients.

Typically, COA provides comments on the Medicare Physician Fee Schedule (“MPFS”) rules, given our physician and independent practice base, but not on the Hospital Outpatient Prospective Payment (HOPPS) rules. However, due to the critical importance of two provisions in the HOPPS Proposed Rule – relating to 340B program changes and laboratory billing (the “14 Day Rule”) – COA is providing specific comments on the HOPPS Proposed Rule.

340B Program Proposed Changes

In short, the 340B program is out of control in the hospital sector. What was originally intended in 1992 as a small-scale program to ensure patients in need did not fall through the “treatment cracks” at a contained number of safety-net hospitals, has mutated into a grossly-abused profit generator for more than half of the nation’s hospitals. The problems with the 340B program in the hospital sector are summarized as follows:

- Only a small minority of 340B hospitals are using the program to benefit patients in need, either directly and/or indirectly.
- Cancer patients in need are being denied care at 340B hospitals and/or placed on special wait lists that slow up their treatment.
• Hospitals, fueled by profit margins of one-hundred percent (100%) or more on expensive cancer drugs, are consolidating the nation’s cancer care system, reducing patient choice and access. This is particularly true for rural and underserved communities with few local oncology providers.
• Cancer care is being shifted away from the private, physician-owned community oncology clinics and into the much more expensive 340B hospital setting, which is increasing costs for Medicare and its beneficiaries with co-pays.
• The increasing scope and magnitude of required 340B discounts are fueling drug prices to record-breaking levels as manufacturers factor these discounts into pricing decisions.

COA completely agrees with the proposals of the Centers for Medicare & Medicaid Services (“CMS”) relating to 340B in the HOPPS Proposed Rule. The proposal will reduce drug costs for seniors by an estimated $180 million a year; help to stop outrageous hospital abuses of the 340B program; and, hopefully, reverse the perverse incentives that have driven the closure and consolidation of our nation’s community cancer care system. The CMS proposals are a great first step in reforming 340B and COA strongly supports them. The 340B program is in desperate need of fixing, as will become apparent in our specific comments that follow in this letter.

Additionally, Congress needs to advance legislation that creates greater 340B program transparency and accountability in hospitals, clarifies the definition of the “340B patient,” and empowers and funds the Health Services & Resources Administration (“HRSA”) to more adequately oversee, monitor, and audit 340B in hospitals.

340B Program Mutation: From Patients to Profits

We trust that CMS is familiar with all the data and analyses on various aspects of the 340B program, specifically in hospitals. We would like to highlight a few important findings related to how the 340B program has severely veered from its original intent and how patient care is being adversely impacted.

Attached is a compilation by COA of the research conducted on the 340B program – The 340B Drug Discount Program in Review: A Look at the Data and Evidence to Date – and a new report we are releasing today – How Abuse of the 340B Program is Hurting Patients – providing actual patient stories of adverse patient impacts. I would like to highlight a few specific points from these documents.

First, studies have documented that the majority of 340B hospitals provide a low level of charity care. A 2016 study by the Berkeley Research Group (BRG), determined that despite the rapid growth in 340B hospitals, there has been no corresponding increase in the amount of charity care those hospitals provide. Given that most 340B hospitals qualify for the program in part based on the number of Medicaid and low-income Medicare patients they serve, there is a presumption that these hospitals also provide relatively high levels of charity care – such as free or discounted care to low-income uninsured or under-insured patients. However, studies on the amount of charity care provided by 340B hospitals suggest that many of these hospitals are providing relatively low levels of charity or uncompensated care.¹

The overwhelming majority of 340B hospitals today provide only a minimal amount of charity care. In fact, for approximately twenty-four percent (24%) of the 340B hospitals studied, charity care represents one percent (1%) or less of hospital patient costs. That is far below the three-point-three percent (3.3%) national average level of charity care for all hospitals, regardless of 340B status, as revealed in an analysis by Avalere Health in 2014. Moreover, the problem is getting worse – since 2011, the number of hospitals with that low level of charity care has grown more than fifty percent (50%).² A 2016 analysis by Avalere of data from 2014 hospital cost reports found that only a very small number of 340B hospitals account for the bulk of overall charity care provided by 340B hospitals. Only

¹ Compliance Trends with Hospital Charity Requirements. BRG, April 2016.
twenty-four percent (24%) of 340B hospitals provide eighty percent (80%) of all charity care delivered by 340B hospitals, despite representing less than half (forty-five percent (45%)) of all hospital beds in the program.3

Second, patients whom 340B was intended to help are often paradoxically harmed by the program, cut off from timely and high-quality care by hospitals seeking to profit from it. We are finding more instances where cancer patients are facing quotas, wait lists, and significantly higher costs at 340B hospitals that prioritize fully-insured patients and the profits they bring. In some cases, 340B hospitals refuse to treat patients in need – the very people the program was designed to help. I call your attention to the real-life stories presented in the attached and just released report – How Abuse of the 340B Program is Hurting Patients. The real stories in this report provide just a small glimpse into how the program has gone off the rails, and is just a sampling of the problems being created by some greedy 340B hospitals. The stories are presented anonymously because local physicians and practices have been punished for speaking out against 340B program abuses by hospitals.

Third, recognizing the tremendous profit they can make from cancer drug arbitrage (buy low, sell high), 340B hospitals have been acquiring independent community oncology practices, which is driving up drug spending for both Medicare and its beneficiaries. As a community oncologist, this is something I have seen firsthand, have heard about from my colleagues across the country, and COA has documented in its Community Oncology Practice Impact Report series. The most recent report published in October 2016, documents that over six-hundred (600) community oncology practices have been acquired by hospitals over the previous ten (10) years.4 An analysis of this data from the previous report found that three (3) out of four (4) of these acquisitions were by hospitals already eligible for 340B. Other hospitals became eligible after the acquisitions. If a practice resists the hospital’s takeover attempts, the next step is most often hospital hard-ball tactics, such as cutting off patient referrals from hospital-owned primary care physicians, regardless of what’s best for cancer patients. (This also happens if practices or physicians attempt to speak out about local hospitals abusing the 340B program).

It is important to understand the finances of 340B, which has become a major money-maker for hospitals and provides substantial motivation to acquire or put independent practices out of business by doing such things as cutting off referrals or stopping hospital privileges. Each oncologist prescribes, on average, between four (4) and six (6) million dollars in chemotherapy drugs every year. So, when a hospital gains 340B eligibility and fifty percent (50%) drug discounts, it can very quickly expect to realize two (2) to three (3) million dollars in profit annually for each oncologist billed by the hospital.

Because of the profit they make from cancer care in 340B, hospitals seek to expand the volume of chemotherapy they deliver by taking over the local and regional cancer care system. Today, more than sixty-two percent (62%) of all Part B outpatient hospital reimbursement for cancer drugs is in 340B hospitals.

The problem with consolidation of cancer care into hospitals is that it is driving up costs for Medicare and all cancer patients, not just Medicare beneficiaries. Looking just at Medicare, a study by the actuarial firm Milliman reported that the consolidation of cancer care into the outpatient hospital setting increased Medicare spending in one (1) year alone (2014) by two (2) million dollars.5 This means that Medicare beneficiaries, responsible for twenty percent (20%) of the cost, incurred increased costs of five-hundred thousand dollars ($500,000) in 2014 alone. All other cancer patients, covered by private insurance, or who self-pay, incurred higher costs as well.

Fourth, the greatly expanding magnitude and scope of 340B discounts are fueling drug prices. As 340B discounts on brand drugs approach, and even exceed, fifty percent (50%), and half of the nation’s hospitals have 340B status, these discounts are factored into drug pricing. This conclusion is supported by discussions with drug manufacturers and data showing a close correlation between the growth of 340B in hospitals and the increase in cancer drug prices.

5 Cost Drivers of Cancer Care: A Retrospective Analyses of Medicare and Commercially Insured Population Claim Data 2004-2014, Milliman, April 2016.
Additionally, we have undertaken an in-depth study analyzing 340B and cancer drug pricing, which should be available sometime in October 2017.

**Recommendations:** We strongly support CMS’ proposals regarding 340B changes in the hospital sector. Although more is needed to curb the 340B program and its abuses – specifically, greater transparency and accountability on how 340B savings are being used, and specific definition of the “340B patient” – we realize that it will require legislation passed by the Congress. Along with these additional changes, we are recommending to Congress that HRSA be given more funding and oversight authority on 340B.

Although decreasing hospital outpatient drug reimbursement at 340B hospitals to average sales price (ASP) minus twenty-two and one-half percent (22.5%) seems severe, as CMS notes in the HOPPS Proposed Rule, *that is a minimum discount*. With 340B discounts on brand drugs approaching, and even exceeding, fifty percent (50%), there is still substantial savings – on the order of fifty percent (50%) drug margins – for hospitals to provide direct and indirect patient benefits using these substantial 340B savings. Our hope is that this reimbursement cut will lessen some of the financial incentive hospitals have to consolidate cancer care into the more expensive setting for Medicare and beneficiaries. However, it will be necessary for Congress to pass legislation dealing specifically with 340B transparency and accountability or we are very concerned that 340B hospitals will start turning away even more cancer patients in need.

Most importantly, we note that Medicare beneficiaries at 340B hospitals will save close to thirty percent (30%) on their copayments. As CMS estimates, this will mean at least one hundred eighty million dollars ($180,000,000) in reduced drug costs for seniors, per year. Ironically, what this reform means is that patients will now directly benefit from the 340B program in terms of lower cost drugs. We note that 340B proponents have stated that if CMS implements this proposal in a budget neutral manner it will not save patients anything – they will save on their drugs but pay increased costs for services. This is not true for cancer patients, where the drug cost is an important component of overall outpatient cancer care costs. Additionally, the CMS proposal in the MPFS to move to greater site payment parity will result in cancer patients who are Medicare beneficiaries paying less for cancer drugs and services.

Given the urgency of this situation, we implore CMS to not reduce the size of the reimbursement reduction and to not phase the reduction in over a two (2) to three (3) year period. We are concerned that if CMS were to reduce the reduction and/or phase it in over time, that 340B hospitals will use that time to aggressively strong-arm independent community oncology practices to sell out to them.

In terms of how the funds saved by CMS are used, we highly recommend that the funds be used to support rural providers – i.e., rural hospitals and other types of rural providers – that are acting as true safety nets for patients in need. As opposed to large hospital “corporations” in urban/suburban areas, rural providers typically operate on lower margins and do catch patients who otherwise would fall through the treatment cracks. This is especially important in cancer care, where the number of rural treatment facilities have declined over the past ten plus (10+) years forcing patients to travel much farther to access treatment, significantly increasing the impact and burden of fighting this devastating disease. There is an urgent need to support rural providers and we highly recommend CMS use the savings from this proposal for this purpose.

Finally, we call CMS’ attention to an important matter that may be an inadvertent loophole relating to biosimilar reimbursement due to current regulation and the CMS proposal regarding drug “pass through” payments. The 2016 Hospital Outpatient Prospective Payment final rule stipulates that subsequent biosimilars – defined as biosimilars after the first to market – do not receive “pass-through” status. Per that final rule (80 Fed. Reg. 70445), CMS commented as follows:

“We appreciate the commenters’ support. We clarify that pass-through payment will be made to the first eligible biosimilar biological product to a reference product. Subsequent biosimilar biological products to a reference product will not meet the newness criterion at 42 CFR 419.64, and therefore will be ineligible for pass-through payment.”

**COMMUNITY ONCOLOGY ALLIANCE**
In the HOPPS Proposed Rule, CMS is proposing that “pass-through” drugs be reimbursed at ASP plus six percent (6%). If implemented as proposed, and given existing regulation regarding “pass-through” status of biosimilars, the first biosimilar to market will be reimbursed at ASP plus six percent (6%) – because it will be accorded “pass-through” status – while all subsequent biosimilars to market in the same category will be reimbursed at ASP minus twenty-two and one-half percent (22.5%), because they will not be accorded “pass-through” status.

The result of this loophole, if the CMS proposal is implemented along with existing regulation, would be to fatally harm the development of the biosimilar market because hospitals will be motivated to exclusively use the first biosimilar with “pass-through” status and the higher reimbursement rate. CMS must rethink the “pass-through” proposal and exclude biosimilars.

“14 Day Rule” Proposed Changes

Medicare's so-called “14 Day Rule” stipulates that molecular testing cannot be billed by the laboratory if ordered within fourteen (14) days of a hospital encounter. The original intent of this rule was to tie costs back to hospital DRG payments made for inpatient services. This rule negatively impacts the ability of providers, such as oncologists, to provide the most appropriate, effective cancer treatment in a timely manner.

Cancer treatment has evolved remarkably over just the past few years, with many therapies relying specifically on DNA and protein testing performed following a biopsy. Currently, these tests cannot even be ordered until two (2) weeks following discharge from the hospital, and many of these tests take two (2) to three (3) weeks before results are available. Typically, the newer targeted therapies work faster with less side effects than conventional treatments and delaying treatment because of outdated regulation risks costing lives.

Currently, hospitals are required to bill Medicare for laboratory tests that they do not perform, that are performed using testing specimens collected during hospital outpatient encounters, and that are unrelated to the outpatient visit, even when those tests are separately paid on the Clinical Laboratory Fee Schedule (“CLFS”). CMS has acknowledged the concerns of stakeholders about this rule in terms of creating unnecessary and complex billing, delaying patient treatment, and hindering the evolution of precision medicine, which is a focus of the landmark 21st Century Cures Act and the Precision Medicine Initiative.

**Recommendation:** We highly recommend that CMS revise this rule to allow laboratories to bill directly for precision medicine testing performed on specimens collected from hospital biopsy specimens. This will ensure that cancer patients have access to the most appropriate and timely treatment. It is important to note that allowing laboratories to bill Medicare directly will not increase costs. In fact, costs should decrease because cancer patients will receive the most personalized and effective treatment, eliminating false-starts and delays.

**Conclusion**

COA appreciates the opportunity to comment on the HOPPS Proposed Rule. We look forward to being a resource to CMS as it examines and reforms the 340B program and stand ready to provide any additional information on the “14-day Rule.”

I can be contacted through the COA offices if there are any questions about this letter.

Sincerely,

Jeffrey Vacirca, MD
President
CC:
The Honorable Kevin Brady, Chairman, Ways and Means Committee
The Honorable Orin Hatch, Chairman, Senate Finance Committee
The Honorable Greg Walden, Chairman, Energy and Commerce Committee