



COMMUNITY ONCOLOGY ALLIANCE

Innovating and Advocating for Community Cancer Care

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September 24, 2018

Submitted electronically to: <http://www.regulations.gov>

The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
P.O. Box 8016
Baltimore, MD 21244-8013

Re: *Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model; CMS-1695-P (the “CY 2019 Proposed HOPPS Rule”)*

Dear Administrator Verma:

On behalf of the Board of Directors of the Community Oncology Alliance (“COA”), I am submitting this comment letter regarding the CY 2019 Medicare Hospital Outpatient Prospective Payment System (“HOPPS”) Proposed Rule (“Proposed Rule”).

COA is a non-profit 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, especially vulnerable seniors with cancer. COA is the only organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving cancer treatment. COA’s mission is to ensure that patients with cancer receive the highest quality, affordable, and accessible cancer care in their own communities. For nearly 16 years, COA has built a national grassroots network of community oncology practices to advocate for public policies to support their patients with cancer.

Ensuring access to affordable life-saving treatments and the highest quality, most affordable cancer care is a top concern for community oncologists. For that reason, we believe that it is important for this administration to focus its reform efforts on the true drivers of health care spending and misaligned incentives. COA applauds the Centers for Medicare & Medicaid Services (“CMS”) for taking decisive steps to address the *real source* of Part B spending increases – namely, the growing shift of care from independent community practices to hospital outpatient departments (“HOPDs”). **Higher costs and utilization of drugs and services in HOPDs, combined with ever-expanding use of HOPDs due to provider consolidation, are driving spending in Part B. CMS has recognized this troubling pattern and in the Proposed Rule the agency outlines several important provisions dealing with site-neutral payments and the 340B program that are intended to level the playing field between hospital and community practice care. This leveling will have the effect of reducing costs to seniors, Medicare, and taxpayers.** As a result, COA fully supports these proposals.

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At the same time, we voice our support for additional site-neutral payment policies and fixing the out-of-control 340B Drug Pricing Program, **COA also cautions CMS to avoid new policies that would result in the unintended consequences of actually further destabilizing independent community oncology and accelerating the shift of cancer care to HOPDs.** We are extremely concerned that any proposals to introduce new third-party middlemen to negotiate Part B drugs will threaten to interfere with quality, accurate, and timely cancer treatment for seniors, our most vulnerable patients. Our experience with middlemen, such as pharmacy benefit managers (“PBMs”), with Medicare Part D and commercial pharmacy benefit plans, is nothing but an increasing nightmare for patients and their providers. Getting patients their cancer drugs on a timely basis is bad enough, but providers also have to routinely deal with middlemen switching drugs and providing incorrect dosages. CMS opening up the door to middlemen in Part B would seriously jeopardize cancer patients’ access to appropriate and timely cancer treatment, while failing to generate any meaningful Medicare savings.

Comments on the Proposed Rule

COA will be providing specific comments and recommendations on the following topic areas in the Proposed Rule:

- **340B Drug Pricing Program:** Proposed 340B Drug Payment Policy to Non-Excepted Off-Campus Provider Based Departments
- **Site Neutrality:** Expansion of Clinical Families of Services at Excepted Off-Campus Departments *and* Proposed Method to Control for Unnecessary Increases in Utilization of Outpatient Services
- **Competitive Acquisition Program (CAP):** Request for Information (RFI) on Leveraging Authority for the CAP for Part B Drugs and Biologicals

Proposed 340B Drug Payment Policy to Non-Excepted Off-Campus Provider-Based Departments (PBDs)

The 340B Drug Pricing Program, as originally intended by Congress, provides a valuable safety net for helping to ensure that America’s most vulnerable uninsured and underinsured patients receive access to critical therapies, including cancer drugs. The program is critically important and COA supports it.

However, growth and abuse of the 340B program hurts cancer patients and the nation’s cancer care system. The program has grown significantly since 2005 and has allowed qualifying hospitals to realize lucrative profits by accessing significant discounts on outpatient drugs. This growth is of extreme concern to COA. In particular, a recent study shows that about one-third of all outpatient volume for certain types of cancer treatments is now at 340B hospitals, which is undoubtedly putting upward pressure on the cost of these therapies.¹

Moreover, the opportunity for 340B hospitals to get substantial revenue from cancer drugs has created financial incentives for hospitals to expand oncology services, notably through acquisition of independent community oncology practices. When oncology practices purchased by 340B entities become off-campus provider-based departments, they also become eligible for 340B discounts, thus further fueling the program’s staggering growth. The 2018 COA Practice Impact Report data shows that over the last decade 658 community oncology practices have been acquired by hospitals, and 3 out of 4 of these acquisitions were by hospitals already eligible for 340B.^{2,3}

COA applauds the administration for already implementing important changes to drug reimbursement for 340B hospitals in last year’s HOPPS rule. Effective January 1, 2018, the agency instituted a payment reduction from average sales price (“ASP”) plus 6% to ASP *minus* 22.5% for Part B drugs for 340B entities. It should be noted that, even with this change, 340B hospitals still can enjoy upwards of 25% margins on drug purchases which is much more than ASP + 4.3% (what remains after the sequester cut is accounted for) that independent, non-HOPD community providers receive.

¹ Berkeley Research Group. Measuring the Relative Size of the 340B Program. July 2017. http://340breform.org/wp-content/uploads/2017/02/July-2017-BRG-White-Paper_Percent-of-Sales.pdf

² Community Oncology Alliance. “Community Oncology Practice Impact Report: Tracking the Changing Landscape of Cancer Care. October 2016. <https://www.communityoncology.org/wp-content/uploads/2016/09/PracticeImpactReport-2016-Report.pdf>

³ Community Oncology Alliance. Community Oncology Practice Impact Report: Tracking the Changing Landscape of Cancer Care. October 2018. <https://www.communityoncology.org/portfolio-items/2018-coa-practice-impact-report/>

The previous change is a huge step forward to reforming the perverse incentives of the 340B program, but it has still not created a level playing field.

For CY 2019, CMS proposes to close an important loophole and apply the payment cuts to non-excepted off-campus PBDs owned by 340B hospitals. COA fully supports the administration's efforts to reform the 340B program to reduce the financial windfall for hospitals and their child sites, while also decreasing costs to Medicare and its beneficiaries.

As noted above, COA believes that the growth of Part B drug spending in recent years has been disproportionately driven by higher costs in the hospital outpatient setting. According to MedPAC, Part B drug spending has grown more rapidly for HOPDs than for physicians and suppliers. Between 2009 and 2015, Part B drug spending grew at an average annual rate of 15.9% for HOPDs and 6.4% for physicians and suppliers.⁴ Moreover, MedPAC found that over half of Medicare Part B drug spending in HOPDs in 2015 was attributable to hospitals that participate in the 340B drug pricing program and purchase drugs at sharply discounted prices.⁵ The 2018 MedPAC Data Book also shows that the shift to hospital spending is happening even faster for oncology products than other Part B drugs.⁶

We note that 340B supporters, and even the press, have erroneously linked COA's position on 340B to that of pharmaceutical manufacturers, especially because we have corporate members. However, COA's position on 340B has always been clear and unwavering. The 340B drug discount program is an invaluable safety net for patients in need. However, over the last 20 years it has mutated from a small safety net program meant to ensure that a handful of hospitals could stretch scarce resources to service those patients in need, to a behemoth money-making machine for hospitals, especially corporate "non-profit" health systems. 340B provides the incentives for hospitals to consolidate cancer treatment to maximize 340B profits from increasingly expensive cancer drugs. This results in two major problems. First, cancer care costs increase – as has been documented by numerous studies – for patients, both seniors covered by Medicare and all other patients covered by commercial insurance or self-pay. Costs also increase for Medicare, commercial insurers, and self-insured employers. Second, 340B hospitals, in addition to having no responsibility to disclose how 340B savings are being used to help patients in need, are under no obligation to treat any patients in need. COA has documented⁷ numerous cases of where 340B hospitals deny cancer patients treatment or put them on special lists that delay their treatment.

Recommendation: 340B is being abused by an increasing number of hospitals and requires greater transparency and accountability to ensure maximum patient benefit. COA strongly support CMS' reimbursement reforms for both 340B entities and their child sites and believes that this policy is an important step forward in correcting longstanding misaligned incentives. Additionally, we fully support CMS' rebalancing of 340B to decrease what is still a substantial profit margin on drugs but note that hospitals still maintain a significant profit margin on drug purchases that far exceeds independent, non-HOPD, community practices. COA supports 340B discounts tied to and following the patient in need, regardless of where the patient is treated – hospital or independent physicians' office setting – for their benefit. That way, patients in need would be assured of receiving discounts on expensive drugs, such as cancer therapies, regardless of where they are treated. COA absolutely does not want to dismantle the 340B program; we want to fix it so that discounts truly benefit patients in need, not the hospital's bottom line.

Site Neutrality Provisions

As of January 1, 2017, CMS implemented the site-neutral payment provisions of Section 603 of the Bipartisan Budget Act of 2015, which sought to level the reimbursement rates between the hospital outpatient and the independent physician office settings. Specifically, off-campus hospital provider-based departments ("PBDs") that began billing

⁴ MedPAC. Data Book. June 2017. http://www.medpac.gov/docs/default-source/data-book/jun17_databooksec10_sec.pdf

⁵ Ibid.

⁶ MedPAC. Data Book. June 2018. http://medpac.gov/docs/default-source/data-book/jun18_databookentirereport_sec.pdf?sfvrsn=0

⁷ Community Oncology Alliance. The 340B Drug Discount Program in Review: How Abuse of the 340B Program is Hurting Patients. September 2017. https://www.communityoncology.org/wp-content/uploads/2017/09/COA_340B-PatientStories_FINAL.pdf

Medicare on or after November 2, 2015 are now paid under the physician fee schedule (“PFS”) at 40% of outpatient rates, rather than under the HOPPS⁸. COA has strongly supported those regulatory and legislative efforts in the past. For CY 2019, CMS is further proposing two important changes:

- Reducing the payment rate for hospital outpatient clinic visits provided at all off-campus PBDs to 40% of the OPFS rate. **This provision would apply to non-excepted, excepted, and grandfathered PBDs.**
- Revising payment so that if an excepted off-campus PBD furnishes a new clinical service that it did not furnish during a baseline period (November 1, 2014 through November 1, 2015), the service from the “new” family would be paid under the PFS rather than the HOPPS.

COA applauds the administration for recognizing that site payment parity, whereby health services are reimbursed at comparable rates, regardless of the site of care, should be a priority. Higher Medicare and private payer reimbursement for outpatient oncology services has provided significant financial incentives for hospitals to purchase physician-owned community oncology practices, especially when coupled with the devastating impact of the sequester cut CMS is wrongfully applying to Part B drugs and incentives under the 340B, which we outlined above. As a result, according to MedPAC, aggregate spending on outpatient hospital services increased 113.7% from 2007 to 2016.⁹

Based on CMS’ own data, clinic visits are the most common service billed under the HOPPS. Today, a Medicare patient could go to a health care provider for a routine check-up and the federal government might end up paying a totally different price, depending on whether the provider is considered a physician’s office or a HOPD. While the site-neutral provisions that went into force in January 2017 sought to limit the impact of this payment disparity for future practice acquisitions, the CMS proposal for CY 2019 takes an important step by introducing site-neutral payments for clinic visits to “grandfathered” PBDs as well. This policy is expected to save approximately \$760 million in FY 2019, including \$150 million in reduced beneficiary copayments.

Independent community oncology practices play a vital role in cancer treatment, allowing patients to receive local, high-quality, and affordable cancer care. COA applauds CMS for pursuing proposals that would ensure that reimbursement disparities and payment incentives do not continue to threaten independent community oncology practices’ viability or prevent them from operating effectively and efficiently. The proposals to reduce reimbursement for patient check-ups and limit the ability of excepted PBDs to add new services will save money for both Medicare and beneficiaries, while allowing patients to continue to choose the site of care that is best for them.

Recommendation: COA urges CMS to finalize both site neutrality provisions as proposed. We also strongly support additional legislative and regulatory efforts to create site-neutral payments for all hospitals, general and cancer-specific, for vital oncology (and associated hematology) services, with no exceptions. We especially note that the policy of allowing the 11 dedicated cancer hospitals to charge Medicare significantly more for cancer care is archaic and costly both to seniors and the Medicare program. In fact, in 2012 alone the Government Accountability Office reported that the 11 dedicated cancer hospitals *cost Medicare close to half a billion dollars more* compared to a matched set of teaching hospitals.¹⁰ COA specifically recommends no special carve-outs for dedicated large cancer hospitals that continue to take advantage of Medicare billing exemptions that result in significantly increased costs for beneficiaries, Medicare, and taxpayers.

Leveraging Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals

As COA has expressed in the past, we are *extremely concerned* with the administration’s continued interest in disruptive changes to the current Part B drug distribution system and the way independent community oncology practices are compensated for procuring, storing, and administering complex cancer therapies for just-in-time administration to patients. Even though oncology care is often cited as the therapeutic area where most spending is concentrated, and

⁸ CMS. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. November 2017.

<https://www.ncbi.nlm.nih.gov/pubmed/29231695>

⁹ Ibid.

¹⁰ Government Accountability Office. Payment Methods for Certain Cancer Hospitals Should Be Revised to Promote Efficiency. February 2015.

<https://www.gao.gov/assets/670/668605.pdf>

annual cost is expected to surpass \$170 billion by 2020¹¹, community oncology practices have proven to be both effective in providing quality cancer care and extremely cost efficient. According to a recent analysis, the mean per member per month cost of oncology care, depending on diagnosis, was 20% to 39% lower for those receiving chemotherapy in an independent community oncology practice compared with the hospital outpatient setting.¹²

Given the scrutiny over spending growth in the Medicare Part B program, CMS is seeking comments on a potential demonstration that would build upon the Medicare Part B drug Competitive Acquisition Program (“CAP”) in effect between July 2006 and December 2008. Even though the exact parameters of this new CAP-like model remain unclear, COA is concerned that without very careful consideration of various policy and business dynamics, CMS may either repeat the same mistakes that led to the original program’s suspension or introduce the same access challenges experienced under Medicare Part D. As stated previously in this letter, we have found that middlemen – especially PBMs – are adversely impacting patient care, complicating drug procurement, delaying and denying patients treatment, and driving up costs.

COA believes increasing the role of middlemen would not only not add any benefit to the existing competition and negotiation for Part B drugs but also would be a disaster for cancer patients, especially vulnerable seniors. Middlemen simply become another entity that requires payment along the supply chain, thus resulting in increased out-of-pocket expenses for patients. A CAP-like program, especially with the parameters proposed by MedPAC as a “Drug Value Program,” would certainly reduce prescriber autonomy and create a system where patient care is determined by cost concerns rather than clinical appropriateness. **Negotiating drug prices based on formulary restrictions or utilization management is particularly dangerous in cancer care because there are few therapeutic and generic-to-brand substitutes.** Therefore, there is little value in having patients go through the delay and administrative burden that would result from the implementation of these management techniques when there are few clinically appropriate alternatives.

COA also strongly objects to the false and unproven “belief” that physicians, including oncologists, select cancer therapies based on financial incentives rather than the clinical need of the patient. Not only is there no current and accurate data supporting that assumption but studies, including one just published by a research firm, shows exactly the opposite:

“Xcenda tested the hypothesis that prescribers of physician-administered drugs disproportionately prescribe therapies with higher reimbursement rates to financially benefit from larger add-on payments. Xcenda analyzed claims data for Medicare Part B fee-for-service beneficiaries receiving physician-administered drugs for RA, breast cancer (BC), and non-small cell lung cancer (NSCLC) in the office setting. The lack of a strong, positive correlation between drug payment and utilization suggests that physician prescribing is not driven by payment-per-drug administration.”¹³

In addition to not understanding the financial reasons why CMS is attempting to resurrect a dead idea, the CAP model with a vendor-managed formulary would be a strong departure from the physician-directed, evidence-based prescribing that is essential in modern-day cancer treatment. Importantly, people with cancer also heavily rely on access to medically appropriate off-label use of oncology drugs and biologics, which could also be at risk under this demonstration. It seems that in trying to make a failed program work, CMS with CAP, and additionally allowing Medicare Advantage plan sponsors to utilize step therapy and formularies, is actually setting cancer care back a decade. As cancer treatment is becoming more precise and personalized, CMS is moving back in the direction of “cookbook” medicine where one size fits all.

Finally, we want to remind the administration to consider all proposed reforms addressing the way in which Part B medications are managed, distributed, and accessed within the broader context of a shift to value-based care in Medicare and beyond. Both COA and CMS have invested heavily in the Oncology Care Model (“OCM”), an alternative payment

¹¹ Xcenda/AmerisourceBergen. The Value of Community Oncology Site of Care Analysis. September 2017. https://www.communityoncology.org/wp-content/uploads/2017/09/Site-of-Care-Cost-Analysis-White-Paper_9.25.17.pdf

¹² Ibid

¹³ Xcenda. Medicare Physician-Administered Drugs: Do Providers Choose Treatment Based on Payment Amount? September 2018. http://partbaccess.org/wp-content/uploads/2017/06/Xcenda_Provider-Utilization_2018-09-10_XD.pdf

model we believe can be a great success for both patients and providers. CMS must consider the impact its proposals to change the Part B program would have on patients and other ongoing value-based models. OCM practices are leading the way in innovative cancer care, and they have carefully weighed their options and the complex interplay between the current reimbursement system and other payment incentives. Burdensome changes to the current very efficient in-office drug delivery system could disrupt the delicate balance of the interaction between current value-based programs and would result in negative consequences for both providers and the patients they serve. It would be an unfortunate loss of years of effort and resources if implementing a CAP-like program threatens quality and cost performance under the OCM.

Recommendation: COA is very concerned about the negative patient impact resulting from proposed changes to the Medicare program that would introduce third-party middlemen to the Part B program. We urge the administration to focus on more viable and patient-centric alternatives. First, as already outlined in this letter, policy solutions should be focused on the real drivers of Part B drug spending, such as HOPDs, and in particular 340B hospitals. Second, COA urges CMS to not implement proposals that would introduce the gross-to-net drug bubble, access restrictions, and care delays currently caused by middlemen in Part D into Part B.

We recommend that if the administration is determined to allow increased utilization management in Part B, it should do so by giving the right tools and incentives to physicians themselves, instead of PBMs and other middlemen CAP vendors. Physicians are increasingly placed at risk under various Medicare programs, but lack tools to manage the risk that is placed upon them. A potential physician-led management program would protect clinical decision-making, and evidence-based care much more effectively than other entities whose decisions are purely based on cost. COA has been engaging with other stakeholders and we see a great opportunity to empower providers to ensure most appropriate and value-based prescribing without jeopardizing patient access or timely care.

Additionally, we recommend that CMS consider a “provider-led” CAP model whereby providers such as community oncology practices, or a non-profit entity like COA, could be the “CAP vendor” and develop/implement provider-drug manufacturer performance-based arrangements, such as indication and outcomes pricing. Currently, CMS uses an innovative approach in the Bundled Payments for Care Improvement Initiative program called a convener entity; basically, a third party, which can also be a hospital/provider and that bears financial risk and assumes the interactions with CMS, much like a CAP vendor. Anti-Kickback Statute (“AKS”) and beneficiary inducements Civil Monetary Penalties (“CMP”) waivers could apply in order for a practice or some collective of physicians to do this or, alternatively, a spinoff of a non-profit, such as COA, which would be the entity.

The rationale for a provider-based CAP model is twofold. First, it keeps out the middlemen that interfere with effective and efficient cancer care and that extract a financial toll on the delivery system, which is already burdened with funds being siphoned off that increase costs to Medicare and its beneficiaries. Second, it allows providers, such as community oncology practices, to implement more sophisticated, performance-based drug pricing/payment/contracting payment models. This includes the ability to implement models such as indication-specific pricing whereby a drug has different prices based on indication or a variation of outcomes pricing/contracting. COA has spent a lot of time/effort in developing the OCM 2.0, an evolved, simpler version of the current OCM. Rather than include drugs in the “backhanded” fashion of the OCM, whereby there are artificial pricing and novel therapy adjustments, the OCM 2.0 will contain performance-based drug pricing. The problem is that with Medicare, the OCM 2.0 would require AKS and CMP waivers, among others. We believe that a CAP provider-based model would be patient-centric and provide the most appropriate evidence-based medical care, employing utilization management, while directly involving drug payments based on value. Finally, we note that CMS has a fiduciary responsibility to its beneficiaries and a financial responsibility to taxpayers to provide optimal medical care that is cost efficient. We believe that a provider-led CAP model based on evidenced-based cancer care will fulfill those responsibilities.

We would welcome the opportunity to discuss our ideas with CMS in greater detail and look forward to engaging on this issue further.

Conclusion

COA appreciates the opportunity to comment on the Proposed Rule and trusts that CMS will carefully consider the changes it has proposed and the impact they will have on the medical care seniors with cancer receive under the Medicare program. Clearly, they should receive the very best, highest quality, and most affordable cancer care that is in step with modern day medicine.

We look forward to working closely with CMS leadership and staff to advance meaningful, patient-centered policies relating to cancer care. We are available to discuss any of our concerns and recommendations provided in this letter and thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'JH', with a long, horizontal flourish extending to the right.

Jeffrey Vacirca, MD, FACP
President