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Innovating and Advocating for Community Cancer Care

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September 27, 2019

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-1717-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; Price Transparency of Hospital Standard Charges; etc. *CMS-1717-P*

Dear Administrator Verma:

On behalf of the Board of Directors of the Community Oncology Alliance (COA), we are submitting this comment letter regarding the CY2020 Medicare Hospital Outpatient Prospective Payment System ("HOPPS") Proposed Rule, *Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; etc. CMS-1717-P* ("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 non-profit 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. For more than 16 years, COA has built a national grassroots network of community oncology practices and physicians to advocate for public policies to support patients with cancer and their provision of care in the most effective and cost-efficient ways. At the core of our mission is the transformation of the health care system focusing on a patient-centered model of care.

COA is dedicated to ensuring patients are able to receive the highest quality, most affordable care in their communities, close to home, from oncology providers. Achieving this goal requires federal policies to correct misaligned financial incentives that drive spending and costs for some of the most vulnerable cancer patients: Medicare beneficiaries. It also requires efforts from the federal government to increase patient access to information about their healthcare costs so that they can make informed decisions about their care with their community oncologist. For these reasons, we are pleased to see provisions in the Proposed Rule that would **increase transparency into**

hospital pricing, continue to **address flaws that drive costs and steer benefits away from the intended population in the 340B program**, and complete efforts to **increase site neutrality** between hospitals and the more affordable community oncology practices.

Comments on the Proposed Rule

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

- **Price Transparency:** Proposed Requirements for Hospitals to Make Public a List of Their Standard Charges
- **340B Drug Pricing Program:** Proposed Continuation of ASP-22.5% Payment Policy for Separately Payable Non-pass-through Drugs Acquired Through the 340B Program
- **Site Neutrality:** Method to Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)

Proposed Requirements for Hospitals to Make Public a List of Their Standard Charges

For years, COA has expressed serious concern to CMS about the harmful trend of consolidation of independent oncology practices into hospitals and the general shift of care toward the more expensive hospital setting. The COA 2018 Community Oncology Practice Impact Report found that 1,653 community oncology clinics and/or practices had closed, been acquired by hospitals, merged, or reported financial struggles since 2008.[1] As this trend continues, costs of cancer care will only increase for the federal government, as the cost of hospital outpatient department (HOPD)-managed chemotherapy has been found to be, on average, 34% higher than physician office-managed care.[2] In fact, a Milliman study found that the shift of chemotherapy infusions from independent community cancer clinics to hospitals cost Medicare an additional $2 billion in 2014.[3]

In an effort to increase price transparency in the *increasingly* expensive hospital setting, CMS is proposing to require hospitals to make standard charges for items performed in the inpatient or outpatient hospital setting publicly available online in digital and machine-readable files. This reporting requirement would include standard gross charge data and payer-specific negotiated charges for at least 300 shoppable services, enforced by monitoring and various penalties. **COA applauds CMS for this proposal to increase transparency into currently opaque hospital pricing.** Requiring price transparency is a positive step that has the potential to slow the shift of care toward more expensive sites of service by arming patients with information about healthcare costs in their decisions about where to seek care, and potentially discouraging hospitals from charging prices that many vulnerable cancer patients cannot afford. We also believe this proposal will help to shine a light on the site-of-care price differences that we know have been fueling consolidation and increased costs to Medicare and cancer patients. Although we think that the push towards price transparency is a great first step, we want to stress that cancer is a complex disease and it is unclear the extent to which the 300 "shoppable" services that hospitals are

[1] https://www.communityoncology.org/2018-Community-Oncology-Practice-Impact-Report/

[2] https://www.communityoncology.org/pdfs/Avalere-Cost-of-Cancer-Care-Study.pdf

[3] http://www.milliman.com/insight/2016/Cost-drivers-of-cancer-care-A-retrospective-analysis-of-Medicare-and-commercially-insured-population-claim-data-2004-2014/

expected to report would include ones that are important to oncology patients. Lastly, we urge CMS to ensure that there are robust mechanisms to ensure compliance with this requirement.

Proposed Continuation of ASP-22.5% Payment Policy for Separately Payable Non-Pass-through Drugs Acquired Through the 340B Program

In the 2019 OPPS final rule, CMS extended the ASP-22.5% payment rate for Part B drugs acquired through the 340B program to non-expected off-campus provider-based departments (PBDs), a decision that COA strongly supported as a means to address misaligned incentives in the 340B program. In the 2020 Proposed Rule, CMS is proposing to continue the ASP-22.5% payment rate in the HOPD and PBD settings in CY 2020. Acknowledging the ongoing litigation related to the ASP-22.5% payment rate, CMS seeks comments on alternative payment options as well.

COA strongly supports CMS's proposal to continue the ASP-22.5% payment in the HOPD and PBD settings. As we have written to CMS many times, we are strong supporters of the 340B drug pricing program as it was originally intended to serve indigent patients across the United States in accessing affordable medicines by providing 340B discounts to a small, defined set of hospitals to stretch "scare resources." However, we continue to be disappointed that a lack of oversight has allowed many hospital health systems to take advantage of the program's payment structure for financial gain. As a result, the 340B program has grown far beyond its original purpose to help America's most vulnerable patients access the drugs they need. Instead, bad actors with massive 340B profits are conducting abusive practices, such as aggressive debt collections, are benefiting. The 340B program has clearly mutated from a patient benefit, especially for those most in need, to a massive hospital profit center with absolutely no accountability.

For example, by using contract pharmacies, 340B covered entities such as certain hospitals are able to profit from the difference between the contract pharmacy's reimbursement from third-party payers and the 340B acquisition cost. According to a recent Drug Channels analysis, these profits can be up to $1,000 per prescription.[4] Entities taking advantage of loopholes such as this have caused the 340B program to grow out of control. Discounted 340B purchases reached a record $24.3 billion in 2018, 26% higher than in 2017.[5] Participation in the 340B program grew from a few hundred entities in 2005 to more than 12,000 qualifying entities and 38,000 total sites in 2017.[6] As a result, about *one-third of all outpatient volume* for certain types of cancer treatments is now at 340B hospitals.[7] This unprecedented growth has resulted in unprecedented costs. Since 2014, purchases made through 340B have grown at an average rate of 28% per year, while manufacturers' net drug revenues have grown at a rate of below 5%.[8] Lack of transparency and oversight in the program prevent us from knowing who is benefiting from the money involved in increased 340B purchases, but it certainly is not the vulnerable patients the program was intended to benefit.

[4] https://www.drugchannels.net/2019/08/Heres-How-PBMs-and-Specialty-Pharmacies.html
[5] https://www.drugchannels.net/2019/08/340B-Program-Purchases-Reach-243.html
[6] https://www.drugchannels.net/2018/07/Our-Exclusive-Analysis-Nearly-One-in.html#more
[7] http://340breform.org/wp-content/uploads/2017/02/July-2017-BRG-White-Paper_Percent-of-Sales.pdf
[8] https://www.drugchannels.net/2019/08/340B-Program-Purchases-Reach-243.html

Despite the ongoing litigation on the issue, COA believes that CMS' proposal to the lower payment rate for Part B drugs at 340B entities to ASP-22.5% helps to reduce the abuse occurring in the 340B program. Because this is done in a site-neutral manner, funds are not taken out of the hospital system but simply more equitably distributed between drugs and services. Those large health systems profiting off of 340B the most, for example, by aggressively expanding their affiliations with contract pharmacies, are those most concerned about the redistribution of CMS hospital funding. We also note that pharmacy benefit managers (PBMs) are now benefiting from 340B by becoming contract pharmacies. PBMs aggressively follow the money so this shows problems with the 340B program mutating from its original congressional intent.

COA fundamentally believes that discounts provided through the 340B program must **follow the patient**, regardless of the site of care. That way, discounts will benefit the vulnerable patients they are intended to help, rather than only benefiting the financial interests of the entity providing their care. This will require efforts from both Congress and CMS. COA applauds the administration for this proposal to correct misaligned incentives in the 340B program and looks forward to continued efforts to increase transparency and oversight of the program.

Method to Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)

We are pleased to see CMS continues to recognize the importance of improving site neutrality in order to lower costs for both the government and Medicare beneficiaries. Site neutrality is also crucial to supporting the viability of independent community oncology practices, which are harmed by reimbursement disparities and misaligned payment incentives. Community oncology practices provide local, high-quality, and affordable cancer care. Site-neutral payment is necessary to support the vitality of community practices so that the patients can benefit from the value these practices provide.

Beginning in 2017, in implementing the site-neutral payment provisions of Section 603 of the Bipartisan Budget Act of 2015, off-campus PBDs that began billing Medicare on or after November 2, 2015 began receiving payment under the physician fee schedule at 40% of outpatient rates, rather than under the HOPPS. Last year, CMS reduced the payment rate for hospital outpatient clinic visits provided at all off-campus PBDs to 40% of the HOPPS rate. This includes non-excepted, excepted, and grandfathered PBDs. CMS is now proposing to complete implementation of the 2-year phase-in of this policy for outpatient clinic visits. While we recognize the courts have challenged CMS' authority to update the payment for clinic visits, **COA supports a policy that levels the playing field and improves site payment parity between PBDs and community-based physician practices.**

Higher Medicare and private payer reimbursement for hospital outpatient clinics has provided significant financial incentives for hospitals to purchase physician-owned community oncology practices. This consolidation increases federal spending. According to MedPAC, aggregate spending on outpatient hospital services increased 113.7% from 2007 to 2016.[9] Clinic visits are the most common service billed under HOPPS. CMS projects reducing payment for outpatient clinic visits at PBDs to 40% of the HOPPS rate will save the Medicare program $810 million and

[9] https://www.ncbi.nlm.nih.gov/pubmed/29231695

lower average beneficiary copayments from $23 to $9 in 2020. These are significant savings at a time when the financial viability of the Medicare program is increasingly under pressure. Because of this, we urge further action from CMS and Congress to continue to implement site-neutral reform.

Conclusion

COA appreciates the opportunity to comment on the Proposed Rule. We applaud CMS' efforts to improve price transparency, address misaligned incentives in the 340B program, and support site-neutral payments. These policy changes are critical to supporting the ability of community oncology practices to provide the highest quality, most affordable care to vulnerable cancer payments.

We look forward to working with CMS' leadership and staff to continue to advance policies that support cancer care. We would be happy to discuss any of our comments included in this letter.

Sincerely,

Michael Diaz, MD
President

Ted Okon
Executive Director