The US Oncology Network

January 25, 2018

VIA ELECTRONIC SUBMISSION TO CompetitionRFI@hhs.gov

The Honorable Alex Azar
Secretary of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Request for Information: Promoting Healthcare Choice and Competition Across the United States

Dear Secretary Azar:

On behalf of The US Oncology Network (The Network), I appreciate the opportunity to provide comment on the Request for Information (RFI), "Promoting Healthcare Choice and Competition Across the United States". The Network commends HHS for its commitment to improving competition, curtailing consolidation and encouraging a robust and diverse healthcare marketplace.

Community-based oncology centers, like those in The US Oncology Network, are central to success in the battle against cancer. The US Oncology Network is the nation's largest and most innovative network of community-based oncology physicians, treating more than 850,000 cancer patients annually in over 400 locations across 25 states. The Network unites physicians around a common vision of expanding patient access to the highest quality state-of-the-art care close to home, and at lower costs for patients and the health care system as a whole. Our mission is to help patients fight cancer, and win.

Unfortunately, access to community-based practices has declined over the past decade due to reimbursement policies and regulations that disadvantage independent physician practices in favor of large, complex healthcare systems. The Network appreciates the Administration's efforts to promote competition and supports the advancement of policies and regulations that improve the viability of private practicing physicians which will lower healthcare costs and expand access to care.

We comment below on several State and Federal laws, regulations and policies driving the unwarranted consolidation of community-based practices; resulting in higher healthcare costs, reduced access to care and diminished competition in the healthcare marketplace.

1. What State or Federal laws, regulation, or policies (including Medicare, Medicaid, and other sources of payment) reduce or restrict competition and choice in healthcare markets?

Reimbursement Policies Restricting Access to Community-Based Practices

a. Sequestration to Part B drugs

Since April 2013, the Centers for Medicare and Medicaid Services (CMS) has applied the 2 percent sequestration Medicare provider cut called for under The Budget Control Act of 2011 (P.L. 112–25) to the fixed, pass-through costs of chemotherapy and related cancer-fighting drugs.

Part B drugs are reimbursed at a statutorily established rate of ASP+6%. For many community-based and smaller practices, it is difficult to purchase Part B drugs below the average industry price upon which average sales price (ASP) is based. In addition to accounting for the fluidity of the actual cost of the drug, the 6 percent add-on helps clinicians cover the considerable overhead costs associated with the purchase, handling, storage, preparation, and disposal of anti-cancer therapies.

Because the 2 percent reduction imposed by sequestration applies to the underlying cost of Part B drugs instead of being focused solely on the service fee, many community-based cancer clinics are "under water" on chemotherapy costs. This unsustainable pressure has resulted in hundreds of sites either closing their doors or being acquired by hospitals where reimbursements for outpatient care is significantly higher. A decade ago, 87 percent of cancer patients were treated in community cancer clinics[1]. Now, fewer than 60 percent of patients are likely to receive cancer care in community cancer clinics[2]. This reality is particularly burdensome for Medicare beneficiaries in rural areas and under-served communities. The Network urges HHS to preserve access to community-cancer clinics and adjust application of Medicare sequester to Part B drugs by only applying the 2 percent reduction to the service fee associated with these medications.

b. Self-referral restrictions

The US Oncology Network embraces innovation in both treatment options and care delivery to provide patient access to high-quality, integrated care in the community-based setting. Most practices across The Network offer patients access to traditional cancer care, such as chemotherapy, radiation therapy, on-site lab services, advanced imaging, medically integrated in-office dispensing pharmacies; support services, such as social and financial counseling; and

[1] Submitted Testimony of Dr. Barry Brooks, Keeping the Promise: Site of Service Medicare Payment Reforms, (May 21, 2014), available at http://democrats.energycommerce.house.gov/sites/default/files/documents/TestimonyBrooks-HE-Medicare- Payment-Reforms-2014-5-21.pdf

[2] Community Oncology Practice Impact Report, The Changing Landscape of Cancer Care, (Oct. 21, 2014- , available at http://www.communityoncology.org/pdfs/Community_Oncology_Practice_Impact_Report_10-21-14F.pdf.

cutting-edge innovations in the fight against cancer, including participation in new cancer care models like the Oncology Care Model or access to clinical trials, all under one roof. This integrated model, permitted by the In-Office Ancillary Services provision of the Stark Law, provides coordination and continuity across treatment plans to benefit patient care. Unfortunately, patients still face barriers in accessing this model of cancer care.

For example, Maryland is the only state in the nation that prevents fully integrated community cancer care by restricting the ancillary services community-based clinics can provide. The state only allows certain hospitals to offer dual modality approaches – chemotherapy in conjunction with radiation therapy – putting community oncology practices and patients at a significant disadvantage. The cost of fighting cancer is higher for patients (10% higher co-pays, an additional $650/year on average) and Medicare (14.2% more, an additional $6,500 a year per patient) when provided in the hospital outpatient setting[3]. Allowing community cancer clinics to provide integrated care under one roof provides patients with more choice in their site of care and lowers healthcare costs for Americans.

Additionally, in 2008 CMS issued a clarification limiting the ability of physicians to refer patients to “under arrangement" facilities. This clarification resulted in the prohibition of referrals for emergency radiation treatment if the initial visit occurred in a hospital, emergency room or during hospital rounds. CMS has ruled that since the patient was not first seen in the physician’s practice, any external referral to a facility in which the physician has an ownership would violate the Stark Law. This has a significant impact on cancer patients in areas where there are few radiation therapy facilities, potentially causing patients to travel long distances for their radiation treatment. We urge HHS to revisit this broad policy to ensure that cancer patients are able to obtain necessary treatment in their community.

c. *In-Office Dispensing as In-Network Providers*

Over the past decade, the availability and use of oral oncolytics as an effective cancer treatment option has significantly increased. In comparison to traditional intravenous (IV) chemotherapy treatment, oral oncolytics present an easier, more convenient route of administration for patients. To improve patient access and adherence, many community-based cancer clinics have established integrated in-office dispensing (IOD) platforms or practice-based pharmacies. Under these models, patient care is more responsive and tailored to the state of the patient’s health allowing for improved education, reduced time-to-treatment and enhanced coordination of the care plan. Patients are able to conveniently access their oral chemotherapy prescriptions or other medications at the point-of-care.

[3] Milliman Client Report: Site of Service Cost Differences for Medicare Patients Receiving Chemotherapy. October 19, 2011. Kate Fitch and Bruce Pyenson. http://publications.milliman.com/publications/health-published/pdfs/site-of-service-cost-differences.pdf

Consolidation has impacted every aspect of the healthcare continuum including the pharmacy benefit industry. Recently, IOD practices have experienced a rise in attempts to drive patients to PBM-owned mail order or specialty pharmacies. In 2016, a single PBM with significant market share sought to unilaterally interpret Medicare Part D to only provide for pharmacy-only networks and that IOD and physician-owned pharmacies were therefore necessarily "out-of-network." The PBM also went so far as to issue notices to IOD physicians of the same, alerting that the physician dispensing class of trade would no longer be included in the PBM's Part D network.

A crucial component of the beneficial oral oncolytic model outlined above is the ability for IOD practices and physician-owned pharmacies to be afforded treatment as in-network providers to Medicare Part D plans. To preserve patient access to oral oncolytics dispensed by community-based cancer clinics, The Network encourages CMS to consider regulatory language or commentary that establishes that duly licensed providers authorized by the health practice laws of their state to dispense outpatient drugs to the patients are afforded the same treatment as a pharmacy for the purposes of Part D's any willing pharmacy requirement.

2. What State or Federal laws, regulations, or policies (including Medicare, Medicaid, and other sources of payment) may promote or encourage anticompetitive behavior in healthcare markets?

Federal Reimbursement Policies Encourage Provider Consolidation

a. Site Neutral Payments

Medicare pays facilities owned by hospitals significantly higher rates for the same outpatient services provided in independent physician practices – chemotherapy: $281 vs. $137 [4]; cardiac imaging: $2,078 vs. $655; colonoscopy: $1,383 vs. $625[5]; even a basic E/M visit costs $51 more when performed in a hospital outpatient department (HOPD)[6]. In addition to increasing costs to the healthcare system, this payment disparity encourages the acquisition of office-based physician practices, further restricting patient access to care in the lower cost setting.

Data continues to demonstrate the negative effects that hospital acquisition of independent physician practices has on costs and access. A recent study by Avalere found patients will have a harder time finding independent physicians as hospital ownership of physician practices increased to 1 in 4 in 2015[7]. In the six months from July 2014 to January 2015 alone, 13,000 physician practices were acquired. Community-based cancer clinics have been hit particularly

[4] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program
[5] Location, Location, Location: Hospital Outpatient Prices Much Higher than Community Settings for Identical Services, The National Institute for Health Care Reform (NIHCR): Published online June 2014.
[6] GAO, Medicare: Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform, December 2015
[7] Avalere, PAI: Physician Practice Acquisition Study: National and Regional Employment Changes, October 2016

hard with a 172 percent increase in consolidation into hospitals since 2008[8].

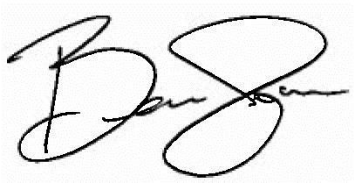
Congress recognized the negative consequences this policy has on our nation's healthcare system and included a site neutral payment provision (Section 603) in the Bipartisan Budget Act of 2015. In 2016, CMS issued a final rule implementing the provision and began aligning payments to all eligible off-campus hospital outpatient departments with payments under the Physician Fee Schedule. Unfortunately, the rule implementing this statutory provision exempted a majority of off-campus HOPDs from the site neutral payment policy, permitting them to continue billing patients and Medicare at the higher rate.

As the new Administration looks for ways to reduce consolidation, improve competition, and provide patients with more health care choices at less cost, The Network encourages HHS to expand site neutral payment policies for all off-campus outpatient services.

Conclusion

The Network appreciates the Administration's efforts to identify and correct policies and regulations that have led to anti-competitive activities and consolidation in the healthcare marketplace. On behalf of the nation's leading community cancer care providers, thank you for the opportunity to provide our comments. Feel free to use us as a resource throughout your tenure as we are happy to provide any additional insight.

Sincerely,



Ben Jones
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[8] Community Oncology Alliance: 2016 Practice Impact Report, October 2016