The US Oncology Network

May 9, 2017

The Honorable Tom Price, M.D.
Secretary of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Reducing Regulation and Controlling Regulatory Costs

Dear Secretary Price:

On behalf of The US Oncology Network, I appreciate the opportunity to provide feedback on President Trump's Executive Order on Reducing Regulation and Controlling Regulatory Costs. The US Oncology Network is committed to working with the Department of Health and Human Services (HHS) to enhance the delivery of cancer care and protect patient access to high-quality care in the most efficient manner. We share your belief that decisions on cancer care, from screening and diagnosis through treatment, should be made within the patient-physician relationship.

Community-based oncology centers, like those in The US Oncology Network, are central to success in the battle against cancer. The US Oncology Network (The 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.

Our dedication to providing high-quality, integrated cancer care is demonstrated by the fourteen oncology practices within The Network, encompassing more than 800 providers, that have been selected to participate in the Centers for Medicare & Medicaid Services' Oncology Care Model (OCM). These practices have accepted the risk of participating in the pilot with the shared goal of improved patient outcomes and cost savings for the Medicare program. We embrace innovation in both treatment options and care delivery, and we are committed to working with you and your colleagues toward policies that enable physicians to practice medicine so that patient outcomes are improved, rather than compromised.

As a physician who has been in private practice, you are well aware of the increasing complexity of practicing medicine in the current regulatory environment. Our healthcare system has experienced sweeping structural changes over the past decade. Most of these changes have taken place under a deluge of regulations, many of which increase administrative burdens for physician practices without conveying a benefit to patient care or improving outcomes.

The Network appreciates the Administration's commitment to regulatory reform, reducing bureaucratic red tape and moving toward a more patient-centered healthcare system. In your quest to identify opportunities for regulatory reform, with a focus on regulations that hinder the patient-physician relationship, we ask that you consider the following:

Applying sequestration to Part B drugs unduly burdens many community-based practices

On April 1, 2013, the Centers for Medicare and Medicaid Services (CMS) began implementing the 2 percent sequestration cut for all providers in Medicare called for under The Budget Control Act of 2011 (P.L. 112–25). Although the Office of Management and Budget (OMB) acknowledged HHS' authority to exercise discretion to lessen the impact of sequestration on core missions, the clinicians upon whom Medicare beneficiaries rely in their battle against cancer have suffered the impact of sequestration on the fixed, pass-through costs of chemotherapy and related cancer-fighting drugs.

As you know, 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, 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 exercise its authority and adjust the manner in which the Medicare sequester is applied to Part B drugs.

Site neutral payment policies offer significant cost savings

As the new Administration looks for ways to reduce regulatory burdens, modernize the Medicare system, and provide patients with more health care choices at less cost, we encourage you to consider the savings associated with adopting site neutral payments for all outpatient services. Data continues to show that patients and Medicare pay more when the same services are delivered in the hospital outpatient department (HOPD) instead of independent physician practices. The increased cost to both patients and Medicare is substantial. Over a three-year period, Medicare paid $23.29

[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.

million more for chemotherapy services solely because they were administered in the HOPD. Cancer patients were forced to absorb an additional $4.05 million in out-of-pocket costs because of the higher patient co-payment[3]. The payment disparity extends beyond cancer care and applies to a wide variety of services – chemotherapy: $390 vs. $136[4]; cardiac imaging: $2,078 vs. $655; colonoscopy[5]: $1,383 vs. $625; even a basic E/M visit costs $51 more when performed in a HOPD[6].

In addition to higher costs to the healthcare system, payment policies that support higher reimbursement in the HOPD setting encourage the acquisition of office-based physician practices, further restricting patient access to care in the lower cost setting. Community-based cancer clinics have been hit particularly hard with a 172 percent increase in consolidation into hospitals since 2008[7].

Congress recognized the negative consequences this policy has on patients, taxpayers and businesses and included a site neutral payment provision (Section 603) in the Bipartisan Budget Act of 2015. Last year, 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 effective January 1, 2017. Unfortunately, the rule implementing this statutory provision exempted a majority of off-campus HOPDs from the site neutral payment policy, permitting them to bill patients and Medicare at the higher rate.

In terms of savings to taxpayers, data suggest site neutral payment across Medicare ambulatory settings has the potential to save $29.5 billion over 10 years. Medicare should be paying the **same amount** for the **same service**; regardless of the setting. The Network encourages HHS to expand site neutral payment policies for all off-campus outpatient services.

Eliminate Medicare Local Coverage Determinations restricting access to radiation therapy services

The Network acknowledges that Local Coverage Determinations are not regulatory actions, however, these sub-regulatory policies can exact a similar, and similarly disproportionate, burden on community cancer clinics and Medicare beneficiaries. For example, on December 1, 2016, Novitas Solutions, Inc. began denying payment for certain radiation therapy services due to a new local coverage determination (LCD) (L36711). The LCD newly restricts the supervision of Intensity Modulated Radiation Therapy (IMRT) services unless a specific subspecialty physician is present on-site, in this case a radiation oncologist. While we fully agree with the need for direct physician oversight when patients receive IMRT treatments, the LCD could result in the closure of numerous community-based clinics as the administration of radiation treatments often spans multiple weeks and many practices do

[3] Berkeley Research Group, "Impact on Medicare Payments of Shift in Site of Care for Chemotherapy Administration," June 2014
[4] Milliman, "Site of Service Cost Differences for Medicare Patients Receiving Chemotherapy," October 2011
[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, Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform, December 2015
[7] Community Oncology Alliance: 2016 Practice Impact Report, October 2016

not have uninterrupted access to a subspecialist on-site. This newly enacted restriction will likely cause serious access issues as cancer patients are forced to travel considerable distances to other sites of care.

The Network prides itself on fostering robust collaboration amongst our 1,400 plus multi-disciplinary physicians. With access to thousands of cancer providers across the country, our centers can leverage and participate in the sharing of best practices to enhance the patient experience and ensure the highest quality of care. In delivering IMRT services, The Network adheres to the American College of Radiology (ACR) practice parameter. The practice parameter specifies that a radiation oncologist supervise the overall process and set up the treatment plan. The radiation therapist performs an authentication simulation to verify that the IMRT plan was correctly imported before proceeding with treatment. Delivery of IMRT services is always directly supervised by a physician onsite.

It is important to note that CMS regulations do not specify clinical qualifications for the supervising provider of radiation therapy services; only that direct personal supervision by a physician is required. Based on decades of experience in providing radiation therapy in secure, high quality, integrated sites, The Network firmly believes that clinically appropriate physician supervision for certain radiation therapy services does not require a specific subspecialty when the services are provided within Novitas' jurisdiction. Clinically appropriate supervision can be performed by physicians who have formal oncology training such as a medical oncologist, pediatric oncologist, and gynecologic oncologist.

In addition to the clinical issues raised above, stakeholders, Members of Congress, and government agencies continue to raise concerns about the lack of transparency and accountability in the underlying LCD process. Novitas' proposed/draft LCD for IMRT did not include the subspecialty provider qualification restriction; it was added to the final notice allowing little time for appeal and reconsideration of the LCD.

In response to concerns raised by The Network and other affected stakeholders, Novitas has postponed the LCD's effective date but still plans to proceed with this unprecedented change of policy.

Our practices take pride in bringing state-of-the-art cancer care and technology to patients across the country, many of whom reside in rural communities. Many of The Network's rural sites cannot support a full-time radiation oncologist due to small volumes. If the LCD is allowed to move forward in its current form, we anticipate disruptions in care and increased travel for Medicare's cancer patients in rural communities. The Network urges HHS to investigate the impact of Novitas' LCD (L36711) restricting access to radiation therapy services and to consider requesting that it be rescinded. We further encourage HHS to ensure that subsequent LCD proposals have an open comment period prior to implementation.

Streamline prior authorization requirements to increase efficiency

The US Oncology Network recognizes that most payers have established prior authorization (PA) requirements to help determine whether a patient's medical condition justifies the services recommended by their provider. In its purest form, the process is designed to safeguard against duplication of services, adverse medical impacts and to minimize unnecessary healthcare costs, especially if there is high variability in patient care amongst differing specialists. However, it appears that the initial spirit behind PA has evolved into an industry upon itself, with many more services requiring PA and the use of third-party vendors to operationalize PA processes. The additional workload translates into higher administrative costs the provider must absorb, as well as increased costs for the payer in implementing these time-intensive programs. For cancer patients, this can create barriers and delays in obtaining timely access to chemotherapy and other essential care.

To further emphasize the impact of PA on medical practices, a study conducted by the AMA showed (on average) 37 PA request per week equating to roughly 16 hours or two business days. In 2013, The US Oncology Network initiated a study on the PA impact and found it costs around $13.09 per PA request. Depending on the volume of requests, a practice may experience increases in administrative costs from tens to hundreds of thousands of dollars, without any improvement in quality of care. Another observation from The Network study also showed most PA requests were ultimately approved, ranging from nearly 95% to over 99%, further validating appropriate care regimens.

The US Oncology Network encourages HHS to streamline relevant Medicare Advantage & Medicaid prior authorization requirements to recognize adherence to agreed upon clinical pathways (such as NCCN) that often eliminate the need for many overly burdensome PA requirements. Alternatively, The Network encourages HHS to consider exempting high-performing and appropriately utilizing practices from PA requirements or mandating expedited reviews.

Increase transparency and oversight over Pharmacy Benefit Manager fees burdening community-based cancer clinics

Availability and use of oral oncolytics has increased significantly over the past decade. Many community-based cancer clinics have integrated physician dispensing platforms and pharmacies into their practices to provide patient convenience, improved adherence and superior outcomes at a lower cost. However, some pharmacy benefit managers (PBMs) have recently taken unprecedented steps to limit or restrict patient access to dispensing facilities and pharmacies in Medicare Part D. For example, we have seen certain dispensing providers at risk of being excluded from network participation. PBMs have also increasingly used retroactive direct and indirect remuneration (DIR) fees as a disincentive for dispensing providers. We urge the Agency to consider additional oversight and increased transparency for PBMs, particularly around DIR fees.

Extend flexibility to rural and low-volume providers with respect to changes in the payment methodology for clinical diagnostic laboratory tests paid under the Clinical Laboratory Fee Schedule (CLFS)

The passage of the Protecting Access to Medicare Act of 2014 (PAMA) required creation of new laboratory payment rates that will be based on an assessment of private market rates reported by applicable laboratories. Concerns have been raised regarding the ability of many laboratories to properly report, accuracy of the data and the impact on low volume providers in rural areas.

Lab services are a critical component of integrated cancer care. By offering these services on-site, community-based cancer clinics give patients timely access to lab tests, enabling quicker results to direct and streamline their treatment plans. However, community cancer centers do not have the volume of many reference labs and would be adversely affected if they were treated as such with respect to payment. We urge the Agency to consider flexibility in reporting and protections for rural and low-volume providers.

Foundation and manufacturer assistance for patient Medicare Part B costs

Many patient advocacy organizations and various pharmaceutical manufacturers have created charitable foundations to provide support to cancer patients in the communities where they live, work and receive treatment. Many of these foundations help ease the burden for families by providing funds for living expenses for eligible cancer patients. However, the foundations face significant hurdles if they choose to provide monetary assistance to help pay Medicare Part B premiums or patient copayments associated with their cancer treatment. We urge HHS to re-evaluate whether these limitations/restrictions are in the best interest of patients in need of financial assistance.

Reconsider translation requirement for patient literature

In May 2016, the HHS Office for Civil Rights issued a final rule implementing a non-discrimination provision of the Affordable Care Act. The new rule requires that Medicare providers take reasonable steps to provide free access to language services for individuals with limited English proficiency that are likely to be seen in their practice. These steps include providing a qualified interpreter free of charge and in a timely manner, posting the non-discrimination notice, and providing patient literature and written materials in the top 15 non-English languages where the practice is located.

We applaud the underlying goal of this new rule and regularly celebrate our patient diversity; however, requiring that practices provide materials in the top 15 non-English languages will have a demonstrable, and disproportionate, financial impact on small and rural practices without a correlating benefit to our patients. While practices are able to use their current stock of publications, once those run out, all forms and patient educational materials must be translated into multiple languages, re-created and printed at the practice's cost. Community-based cancer clinics operate on small margins, and this requirement will impact the practice's bottom line and potentially jeopardize viability.

Community providers know their patients best and can offer these valuable services in a targeted and appropriate manner without the need for a federal mandate. The Network encourages HHS to reconsider the non-discrimination rule and the translation requirement for forms and patient educational materials.

Consideration of rural providers and the cancer patients they serve in revisiting Stark Law applicability to emergency radiation referrals

In 2008, CMS issued a clarification limiting the ability of physicians to refer patients to “under arrangement" facilities. While expansive in nature, 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 emergency radiation treatment in their community if necessary and appropriate.

Conclusion

The US Oncology Network would welcome the opportunity to discuss these issues and others impacting community cancer care with you and your staff in the near future. I can be reached directly at Ben.Jones@usoncology.com to find a mutually convenient date and time for a more substantive discussion.

On behalf of the nation’s leading community cancer care providers, thank you for the opportunity to provide our comments. We are grateful to be able to engage in substantive discussions and welcome practice site visits with HHS and CMS officials. Feel free to use us as a resource throughout your tenure as we are happy to provide any additional insight.

Sincerely,

Ben Jones
Vice President, Government Relations
The US Oncology Network