March 11, 2022

The Honorable Brad Wenstrup
U.S. House of Representatives
2419 Rayburn House Office Building
Washington, D.C. 20515

The Honorable John Joyce
U.S. House of Representatives
1221 Longworth House Office Building
Washington, D.C. 20515

The Honorable Bruce Westerman
U.S. House of Representatives
202 Cannon House Office Building
Washington, D.C. 20515

Dear Representatives Wenstrup, Joyce, and Westerman,

On behalf of The US Oncology Network (The Network), which represents more than 10,000 oncology physicians, nurses, clinicians, and cancer care specialists nationwide, thank you for the opportunity to provide comments to the Healthy Future Task Force Treatments Subcommittee.

The US Oncology Network is one of the nation's largest and most innovative networks of community-based oncology providers, treating more than 1.2 million cancer patients annually in more than 450 locations across 25 states. The Network unites over 1,400 like-minded 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. The delivery of modern cancer care is premised on innovation, which is why we share in the Subcommittee's four primary goals and desire to "supercharge the availability and development of life-saving treatments, devices, and diagnostics, while addressing the rising costs to patients."

The Network is also a worldwide leader in research, offering our patients access to the latest cancer clinical trials close to home through one of the largest clinical research networks, US Oncology Research. The Network, through US Oncology Research, has contributed to the approval of more than 100 FDA-approved therapies since its inception. We have enrolled more than 85,000 patients in clinical trials with approximately 400 active trials across ten disease states at any given time. Patient access to these novel clinical trials is usually limited to major academic centers and urban hospital systems, but we work to provide clinical research in community based cancer clinics to ensure our patients have access to new and novel therapies. The Network is proud to offer access to clinical trials at more than 160 sites across the country where patients have the support of their local communities, and our participation in these efforts accelerates the progress of modern cancer therapy.

In response to the Subcommittee's request for information (RFI), The Network would like to provide comment on the following issues to greatly improve healthcare treatment for American patients.

Innovative Payment Solutions for Expensive Curative Therapies

As part of the Subcommittee's goal to evaluate potential innovative payment solutions for expensive curative therapies in Medicare, the RFI asks whether reimbursement based on site of service should be considered. For example, the Subcommittee noted CAR-T therapy, one of the newest, most groundbreaking, and most promising oncology treatments available, is typically delivered in the inpatient setting. However, clinical trials are being designed specifically to test the feasibility of outpatient CAR T-cell therapy and community oncologists are gaining access to administer the FDA-approved CAR T-cell products. The Network has sites, such as Oncology Hematology Care, Inc. in Cincinnati, Ohio, that are currently offering CAR-T in the outpatient setting through clinical trials to bring this promising technology to our patients. While The Network

has welcomed CMS' approach to coverage of CAR-T, it also encouraged the agency to consider future forms of patient access to the breakthrough treatment, particularly in the community setting, when developing coverage and payment policy. We have specifically urged CMS to embrace coverage and reimbursement of CAR-T therapies across care settings. It important to make novel therapy like CAR-T a reality for more patients close to home, through high value and largely outpatient solutions that seek to lower the cost of cancer care.

Site Neutral Payment Reform

For more than a decade, The Network has raised awareness of the negative consequences payment disparity across sites of service has on our nation's healthcare system. Reimbursement policies that pay hospital-owned outpatient facilities higher rates for the exact same services provided in independent physician practices have increased costs to patients, insurers and taxpayers, as well as resulted in marketplace consolidation that limits patient choice by reducing access to care in the community-setting. We supported the 2018 final rule equalizing Medicare payment rates for clinic visit services performed at off-campus hospital outpatient departments (HOPDs) and independent physician offices to control unnecessary volume increases in the outpatient setting. For these reasons, we share the Subcommittee's interest in site of care delivery policies.

Medicare payment differentials for identical services provided in HOPDs and independent physician offices have been well documented. According to the most recent CMS payment rules, chemotherapy administration is reimbursed $326 in the HOPD setting and only $140 in the physician office setting. Similar trends exist among other commonly billed services, such as cardiac imaging and colonoscopy services.[1] Another recent study found that hospital-integrated physicians would receive $114,000 more in annual Medicare reimbursements for outpatient services compared to non-integrated physicians.[2] According to the *Health Savers Initiative,* Medicare could save nearly $2.8 billion in imaging services and nearly $1 billion in drug administration services by shifting to site neutral payments for all HOPDs.[3] Over 10 years, they find Medicare spending could be reduced by more than $150 billion and beneficiary premiums and cost-sharing could be reduced by nearly $100 billion by transitioning to site neutral payments for all HOPDs.[4]

These disparities not only increase costs to Medicare, but also to patients. Over a three-year period, Medicare paid 27% more ($2.7 billion) and patients spent 21% more ($411 million) for specific cardiology, orthopedic, and gastroenterology services provided in the HOPD setting rather than the community setting.[5] The Network strongly believes that patients and Medicare should be paying the same amount for the same service.

Site of service payment differentials do not just exist in Medicare. According to a 2019 analysis by the *Health Care Cost Institute,* the average price for a given service was always higher when performed in the HOPD setting and average prices rose faster in the outpatient setting compared to the physician office setting. For example:

- The average price for a level 3 diagnostic and screening ultrasound visit increased 4% in office settings from 2009 to 2017, from $233 to $241, and 14% in outpatient settings, from $568 to $650.
- The average price for a level 5 drug administration visit increased 15% in office settings from 2009 to 2017, from $220 to $254, and 57% in outpatient settings, from $423 to $664.
- The average price for a level 4 endoscopy upper airway visit increased 14% in office settings from 2009 to 2017, from $463 to $527, and 73% in outpatient settings, from $1,552 to $2,679.

[1] http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/021919-Avalere-PAI-Physician-Employment-Trends-Study-2018-Update.pdf?ver=2019-02-19-162735-117
[2] https://onlinelibrary.wiley.com/doi/epdf/10.1111/1475-6773.13613
[3] https://www.crfb.org/papers/equalizing-medicare-payments-regardless-site-care
[4] Id.
[5] http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/PAI_Medicare%20Cost%20Analysis%20--%20FINAL%2011_9_17.pdf

- Consolidation also drives up costs in commercial healthcare. When chemotherapy is evaluated by site of service, we observe the cost by drug, by day, and by 6-month episode for cancer patients to be almost double in the HOPD setting compared to physician offices.[6]

Higher cost is one of the driving forces of healthcare provider consolidation, resulting in reduced patient access to community-based care (see oncology-specific acquisition trends below). Unfortunately, HOPD growth is only expected to grow, outpacing the growth of independent physician practices. According to Congressional Budget Office projections, Medicare hospital outpatient payments will grow by 100% over the next decade; by comparison, physician fee schedule payments are only expected to grow by 31%.[7] These projections come on the heels of years of modest reimbursement increases to physicians as hospital outpatient reimbursements have skyrocketed. Independent physician offices remain the highest value site of service for cancer care.

For these reasons, The Network shares the recommendations of the Alliance for Site Neutral Payment Reform as the Subcommittee considers ways to expand site neutral payment policies, including:

- *Expanding site neutral payments to all clinically appropriate outpatient services*. The FY2020 President's Budget called for expanding site neutral payments for all off-campus hospital-owned physician practices. This policy was projected to save approximately $28.7 billion over 10 years.
- *Extending site neutral payments for Part B drug administration*. More narrowly targeted than the above provision, this policy would immediately reduce out-of-pocket prescription drug costs for seniors because Medicare beneficiary cost-sharing is directly related to the Medicare payment rate for the drug and the administration of the drug. This policy is included in H.R. 19, the Lower Costs, More Cures Act of 2021.
- *Improving Medicare site-of-service transparency*. Modify the Medicare Outpatient Procedure Price Lookup tool to include information for services furnished in a physician office. This will empower patients to better understand the variations in cost by site of care and the impact on their out-of-pocket costs. This policy is also included in H.R. 19, the Lower Costs, More Cures Act of 2021.

As the Subcommittee considers site neutral payment reforms, we also would like to highlight that, according to the American Medical Association, Medicare physician pay has actually fallen by 20% over the last 20 years when adjusting for inflation in practice costs.[8] Considering physician payments are frozen indefinitely under current law and subject to the 2% Medicare sequester, while HOPDs are projected to receive another 2% payment increase in 2023, it is clear this payment disparity will only encourage further consolidation.[9] The Network encourages the Subcommittee to evaluate payment parity policies that set reimbursement for cancer drug administration and other cancer care services at a rate that falls between the current higher OPPS rate and the lower rate for physician offices. A new consistent rate shared across settings would support access to community cancer clinics, while removing the unfair payment advantage currently awarded to off-campus HOPDs, while still yielding savings for patients and Medicare.

Value-Based Care and Clinical Pathways

The Network is committed to the delivery of value-based healthcare and its promise to improve care quality, efficiency, and patient outcomes at a lower cost. We are a leader in practice transformation and an integral partner in the transition to value-based cancer care as demonstrated by the more than 900 Network physicians participating in the CMS Innovation Center's Oncology Care Model (OCM), saving the Medicare program a combined $240 million over the course of the demonstration. The Network's OCM practices have made significant investments in practice transformation, changes to clinical workflow and have fully embraced team-based care to improve patient outcomes and show meaningful cost savings.

[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5885220/
[7] https://www.cbo.gov/system/files/2020-03/51302-2020-03-medicare.pdf
[8] https://www.ama-assn.org/system/files/medicare-pay-chart-2021.pdf
[9] https://www.medpac.gov/wp-content/uploads/2021/09/Hospital-update-MedPAC-Dec-2021.pdf

While outcomes-based payment and service delivery innovations are being tested among various patient populations, by episodes of care, and through team-based, coordinated care, more can be done to facilitate this transition across the healthcare ecosystem. The Network has developed evidence-based pathways that focus the wide range of treatment possibilities into more precise, clinically proven options. Clinical pathways have emerged as a key tool driving informed decision making and providing more efficient, cost-effective, value-based care. Adopting evidence-based clinical pathways has helped align patient care and reduce unnecessary variation across the Network. These pathways provide a succinct, clinically proven list of treatment options that offer increased value to the healthcare system and the patient through a careful balance of cost sensitivity, treatment toxicity, and clinical outcomes.

The Network's clinical pathways and review process allows our practices to move quickly to adopt the latest drugs and therapies backed by clinical evidence in order to achieve optimal outcomes for our patients. The Network has been able to successfully adopt pathways to help streamline the integration of evidence-based best practices while improving quality and reducing costs for patients and payers. Our experience demonstrates that value-based clinical pathways—including the rapid integration of new research and treatments into standards of care—can be done safely and effectively.

Clinical pathways reduce the cost of cancer care, increase patient satisfaction, and ultimately improve clinical outcomes. The Network also believes adherence to clinical pathways can play an important role in reforming payer utilization management (UM) policies. For example, physicians aligned with evidence-based clinical pathways should be exempt from prior authorization and step therapy requirements. The Network looks forward to continuing to work with both government and private payers to establish value-based care models that incorporate innovative therapies and technologies.

Value-Based Purchasing for Drugs Covered in Medicaid

As part of our commitment to the delivery of value-based healthcare and its promise to improve care quality, efficiency, and patient outcomes at a lower cost, The Network supported CMS' December 2020 final rule to eliminate barriers to value-based purchasing (VBP) for drugs in Medicaid.

CMS proposed to facilitate the development of VBP arrangements between drug manufacturers, commercial payers, and state Medicaid programs by addressing longstanding regulatory barriers. The rule would provide manufacturers with flexibility in price reporting obligations under the Medicaid Drug Rebate Program (MDRP) for drugs subject to VBP contracts, allowing drug prices under VBPs to be calculated as bundled sales and/or allowing for multiple best prices. These changes would provide manufacturers additional flexibility and certainty in entering into VBP arrangements with payers that tie a drug's price to patient outcomes. The definition and 2 design parameters of VBP arrangements, including the products subject to such agreements and evidence-based or outcomes-based measures assessed, coupled with the contractual requirements between manufacturers and payers, would play a critical role in the success of this proposal. Since The Network is neither a plan nor manufacturer, it would not be party to any of these specific arrangements, however we do support the goals of value-based care to enhance clinical decision making, increase care quality, reduce costs, and improve patient outcomes.

In the same rulemaking process, CMS attempted to clarify the determination of manufacturer price reporting requirements for patient cost-sharing assistance subject to pharmacy benefit manager (PBM) copay accumulator programs. While likely outside the scope of the Subcommittee's inquiry, The Network provided comment on this aspect of the rule, expressing concern that the proposal may unintentionally harm patients. We would be happy to discuss this issue further, if helpful, but broadly speaking, The Network fully supports any and all efforts to ensure patient assistance programs accrue solely to the patient.

Medicare Drug Price Setting

Over the past several years, community oncology providers have been threatened by purported drug price reforms that would undermine the viability of independent practices and jeopardize patient access to local cancer care. Whether the Medicare Part B Demonstration Program, the International Pricing Index, Most Favored Nation Model, or the drug price negotiation program Democrats pursued in recent months, each of these approaches would harm American cancer patients and the oncology innovation pipeline.

The Network remains deeply concerned with the drug negotiation provisions in the Build Back Better Act (BBBA). The provisions direct the Secretary of Health and Human Services to negotiate a Maximum Fair Price for certain drugs in Medicare Parts B and D (particularly, for those drugs that have been on the market for a certain length of time and have no generic or biosimilar competition). The provisions also alter the manner in which providers are reimbursed for administering medications that could lead to unintended consequences to patient care.

While we appreciate efforts to reduce patient out-of-pocket costs that often lead to financial toxicity, a bipartisan effort also captured by H.R. 19, the drug negotiation provisions in the Democrats' Build Back Better Act are unprecedented and wide ranging. We encourage Congress to strongly consider the downstream impact of these policies on community-based practices and the patients they serve; and we further recommend that Congress explore options that avoid adverse impacts to provider reimbursement resulting from any potential negotiation on drugs.

The community-based setting offers cancer patients access to high-quality, cost-effective care in a location convenient to their home, family, caregivers, and support systems. Rather that blunt instrument approaches targeting innovators and providers, Congress should consider addressing payer policies that stand between providers, patients, and their healthcare. The natural consequence of broadly implementing price reduction strategies without consideration for how the changes will impact site of service variability could further consolidation and diminish access to care for Medicare beneficiaries.

Pharmacy Benefit Manager (PBM) Transparency

As Congress considers how to improve treatment access and affordability for American patients, we urge careful consideration of pharmacy benefit manager (PBM) practices. PBMs, which administer the pharmacy benefit for most major health plans, have played a growing role in determining what drugs are available to patients, what pharmacies must be used, and how much patients will pay for their medications. Over the past decade, the nation's largest insurers and PBMs have consolidated and grown, resulting in the three largest PBMs processing nearly 80 percent of all prescription claims in 2020.[10] While the PBM industry claims they maximize negotiated savings for their covered beneficiaries and plan sponsors, the real world evidence suggests PBMs interfere with the doctor-patient relationship, drive up healthcare costs, and can even delay delivery of life-saving treatments.

The concerns with PBM practices are numerous and ever-evolving, including exponential increases in pharmacy price concessions (also known as direct and indirect remuneration, or DIR fees), narrowing pharmacy networks, and increased steerage toward PBM-affiliated pharmacies – some of which is even mandated through "white-bagging" policies discussed below. Nearly all of these policies have the effect of increasing PBM profits at the expense of patients and plan sponsors. While each of these concerns should be addressed, the current PBM industry has flourished due to a lack of transparency. One of the first steps Congress should consider is how to inject sunlight into the operation of PBMs.

[10] https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html

The Network appreciates the attention House Republicans have paid to the PBM practice known as “spread pricing.” This involves PBMs charging plan sponsors a high price for a drug that is then reimbursed to providers at a much lower rate, creating a “spread” that is kept by PBMs, driving up profits. This practice also contributes to the strain PBMs impose on The Network’s medically integrated pharmacy services, including physician-administered oncology drugs. Ultimately all of these PBM practices drive up the cost of life-saving medications for cancer patients. The Network supports introduced legislation to insert transparency into spread pricing practices, such as H.R. 6101, the Drug Price Transparency in Medicaid Act of 2021. This policy was also included in H.R. 19, the Lower Costs, More Cures Act of 2021. The Network also supports the House Committee on Oversight and Reform’s November 2021 forum reviewing the role PBMs play in pharmaceutical markets.

Prior Authorization Reform

The Network encourages the Subcommittee to examine the rising use of prior authorization, which continues to burden physicians and clinical staff, increase practice operating costs, and delay time-sensitive care for patients. Such policies are a direct threat to integrated care. They place a middleman with unknown medical expertise between a patient and the personalized treatment plan developed by their physician. Prior authorization policies with appeal procedures that are deliberately difficult and driven by cost containment goals rather than patient outcomes are prohibitively high barriers to innovative, FDA approved therapies. The Network encourages the Subcommittee to consider opportunities to streamline prior authorization requirements and recognize of the impact of adherence to agreed-upon clinical pathways.

For cancer patients, access to timely and individualized care is paramount. Oncologists work closely with their patients to develop personalized treatment plans by evaluating each patient’s medical history, the presence of comorbidities, potential drug interactions, type and stage of cancer, specific mutations present, and intent of therapy, in addition to other patient and/or disease-specific factors. Prior authorization requirements interfere with the doctor-patient relationship by allowing a third-party to deny a treatment that has been prescribed based on a physician’s assessment of clinical need. A patient may experience irreversible disease progression as they wait to receive the intended drug or treatment protocol initially prescribed by their oncologist.

Practices often employ multiple full-time employees devoted to navigating utilization management protocols across multiple payors, requiring significant investment in both human capital and infrastructure. A 2021 survey by the American Medical Association found that more than 93 percent of surveyed physicians reported care delays as a result of prior authorization, 34 percent reported prior authorizations lead to a serious adverse event and 82 percent reported that the burden associated with prior authorizations led to treatment abandonment.[11]

Standardized and streamlined prior authorization processes can serve to improve efficiency, facilitate shorter response timelines, and allow patients to access necessary therapies in a timely manner. A single electronic prior authorization standard with stakeholder buy-in would reduce the burden of prior authorization for both payers and providers. It would also serve to clarify prior authorization requirements for patients and prescribers. One such measure that would streamline prior authorization in Medicare Advantage plans is H.R. 3173, the Improving Seniors’ Access to Timely Care Act, which currently has 261 bipartisan cosponsors.

Step Therapy Reform

Relatedly, The Network has long advocated for review of step therapy policies and their impact on patient access to innovative and personalized therapies. Also known as "fail first," step therapy forces patients to try

[11] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5885220/

a drug that is preferred by their insurance plan before they can proceed to the drug prescribed by their physician—even if the patient has tried and failed on a drug while covered under a previous health plan. As medicine becomes more and more tailored to the unique traits of individual patients, step therapy policies continue to force patients into a one-size-fits-all model of care that prioritizes potential cost saving over individualized treatment and patient health outcomes. The Network believes that providers are best suited to direct treatment to less expensive medications without compromising clinical efficacy.

When the first and second therapy options fail for a patient or are contraindicated because of a patient's medical history, physicians lean heavily on their extensive medical expertise and years of training to pinpoint alternate treatment options. Step therapy ignores and devalues this expertise. By hindering patients' access to the most innovative, potentially effective treatment options, step therapy is incompatible with standards of patient care and a clinician's medical acumen that can incorporate the nuance and expertise from multiple years of training and practice in making optimal choices for patients.

Step therapy policies are not clear or consistent across payers, including Medicare, causing needless confusion for both patients and providers. These burdensome policies divert critical time physicians could spend with patients and instead force them to dedicate their attention to a lengthy, bureaucratic, opaque appeals process. They also infringe upon the doctor-patient relationship that lies are the core of our health care delivery system by allowing insurance plans to decide which medicines a patient should take.

Considering the Subcommittee has placed a priority on access to innovative therapies, the clinical impact of step therapy should be addressed. Ideally, while insurers would require physicians to begin treatment with an insurer-required drug that is both more effective and less costly, there are reported instances of insurers requiring patients to fail first on a drug that is more expensive. When insurers implement step therapy policies that force patients to try a brand drug before a biosimilar, this not only impedes the physician from selecting the most appropriate drug for his or her patient but it also reduces the uptake of biosimilars and ultimately results in higher costs across the health care system.

Rather than force patients into a one-size-fits-all approach, The Network would again encourage lawmakers to embrace proven methods, such as evidence-based pathways programs, to drive value-based treatment choices. Regarding step therapy reform, The Network supports Rep. Wenstrup's Safe Step Act, H.R. 2163, to place reasonable guardrails on the practice for group health plans.

"White Bagging" Reform

Treatment for cancer care is highly personalized and tailored towards each individual patient. For example, chemotherapies consist of complex drug regimens that are dynamic and frequently adjusted at the point of care based on a patient's ever-changing circumstance. In our practices, highly trained physicians safely stock, monitor, and administer our patients' treatment. This enables physicians across the Network to make the day-of dose adjustments and drug substitutions or additions necessary to effectively treat the unique needs of each patient and their disease. These same day dosing changes occur frequently in cancer care.

Network practices utilize a closed supply distribution system that ensures the integrity of all products given to patients. All drugs are shipped directly from the manufacturer to an authorized distributor and then to our practice in containers that protect them from adverse environmental conditions. This system helps ensure timeliness of care, a critical component of successful treatment.

As described above, in recent years several of the nation's largest insurers, pharmacy benefits managers (PBMs), and specialty pharmacies have consolidated. This vertical integration has enabled insurers to gain greater control of downstream pharmacy and provider assets, enabling PBMs to expand their monopoly into specialty drugs. Many payers are starting to require their members to obtain certain physician-administered

drugs only through their specialty pharmacy, instead of through the patient's physician office. This process is known as "white-bagging."

Under a "white bagging" arrangement, a patient's insurance company requires the drug to be purchased through the insurer's exclusive specialty pharmacy of choice and then shipped to the oncologist's office for administration to that specific patient. This complex requirement can interrupt the course of care and contribute to the progression of disease; patients must wait until the drug is delivered to the oncology practice to receive treatment and day-of-dose adjustments or drug substitutions or additions are no longer possible. Additionally, white bagging typically transitions payer reimbursement from the patient's medical benefit to the pharmacy benefit, which often increases the patient's out-of-pocket expenses.

Several states have considered or passed legislation to prohibit payer-mandated white bagging requirements or reduce its burden. The Network applauds these efforts and encourages the Subcommittee to consider policies that address this widespread issue on a national level.

Conclusion

Thank you for the opportunity to comment on these important issues. We welcome the opportunity to discuss them with you or your staff in more detail. Should you have any questions, please contact Ben Jones, Vice President of Government Relations and Public Policy, at Ben.Jones@usoncology.com.

Sincerely,

Debra Patt, MD, PhD, MBA
Chair, Public Policy & Reimbursement Committee
National Policy Board
The US Oncology Network