

August 2, 2024

The Honorable Larry Bucshon, M.D.
U.S. House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

Re: Request for Information on 21st Century Cures Initiative

Dear Representatives Bucshon and DeGette:

On behalf of The US Oncology Network (The Network), which represents over 15,000 oncology physicians, nurses, clinicians, and cancer care specialists nationwide, thank you for the opportunity to provide input on the 21st Century Cures Initiative and efforts to spur the next generation of treatments. We applaud your steadfast dedication to advancing patient-centered medical research for the most challenging diseases and disorders, from basic research to clinical testing to cures.

The Network is one of the nation's most innovative networks of independent, community-based oncology physicians, uniting over 2,400 like-minded physicians around a common vision of expanding patient access to high quality, state-of-the-art care close to home and at a lower costs for patients and the healthcare system. Practices in The Network treat over 1.4 million cancer patients annually in more than 600 locations across 31 states.

Along with delivering comprehensive cancer care close to home, The Network is also a worldwide leader in cancer research. Many practices in The Network offer their patients a chance to participate in some of the most advanced cancer clinical trials available today. Our treatment centers have contributed to the approval of more than 100 FDA-approved therapies since its inception. Practices in The Network have enrolled more than 88,000 patients in oncology clinical trials in communities across the country and contributed to 100 FDA-approved cancer therapies. At any one time, more than 500 oncology clinical trials are in progress across The Network. We believe that it is this kind of medical research that fuels innovation, propels medicine forward, and yields transformational cures for patients.

We appreciate the work of the 21st Century Cures initiative, which encouraged government-funded cancer research through the National Institutes of Health (NIH), the Cancer Moonshot initiative, and the Advanced Research Projects Agency for Health (ARPA-H). As you develop the next iteration of 21st Century Cures, we encourage you to recognize the important role the community-based setting plays in clinical trials, and we offer the following policy considerations to promote access to life-saving cures:

- Recognize the role of community oncology as you develop any public-private partnerships for cancer research and clinical trials;
- Expand access to telehealth in clinical trials; and
- Provide coverage of genetic counselor services in Medicare

The Role of Community Oncology in Clinical Research and Trials

Practices in The Network offer truly integrated cancer care by providing a comprehensive range of services all under one roof. These services include chemotherapy and biological therapy, hormonal therapy, immunotherapy, radiation therapy, advanced diagnostic and laboratory services, clinical research, support services like nutrition or financial counseling, and

medically-integrated dispensing. Patients respond best to treatment when they receive integrated care close to home, where they have the support of family and friends and can maintain their daily routines throughout the treatment process. As a result, the community cancer model is focused on serving patients where they live and work, so they don't have to travel long distances to receive high-quality treatment.

Patient access to 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, and our participation in these efforts accelerates the progress of modern cancer therapy.

In 2022, The Network formed a deeper partnership with the Sarah Cannon Research Institute (SCRI) to further expand access to clinical trials in the community setting. SCRI is a dedicated cancer treatment center renowned for its expertise in cancer care and clinical research. SCRI offers patients state-of-the-art personalized cancer care and opportunities to participate in clinical trials with innovative treatments. It is the only oncology research organization of its kind that provides end-to-end clinical trial site management, contract research services for biopharma, and personalized medicine advisory services. Through The Network's partnership with SCRI, we are expanding clinical research, accelerating drug development, and increasing the availability and access to clinical trials for community oncology providers and patients, including those in underserved communities.

Through our partnership with SCRI, The Network has expanded its rural footprint and increased access to a diverse patient population. As trials work to develop more innovative therapies, it is important that as many patient populations are included as possible to fully account for the diversity of biologic, social, and cultural factors that influence outcomes.¹ The National Institute on Minority Health and Health Disparities emphasizes that clinical trials include people with a variety of lived experiences and living conditions, as well as characteristics like race and ethnicity, age, sex, and sexual orientation, so that all communities can benefit from scientific advances.²

During the public health emergency, it was critical that COVID-19 vaccine trials included sufficient representation across population groups to understand effectiveness in various populations who have different lived experiences and exposures.³ With practices in over 30 states, and nearly 85 percent of patients with cancer being treated in the community setting⁴ our physicians have unique access to a diverse patient population. The community-based setting thereby increases the opportunity to enroll patients with diverse socioeconomic backgrounds, race/ethnicity, and geographic location.

As Congress develops the next iteration of Cures, we encourage you to recognize the value and role of community oncology in providing access to a unique geographical and diverse patient population for clinical research and trials. Our goal is to offer greater access to clinical trials for more patients and physician researchers. We urge you to consider community oncology as you develop any public-private partnerships for cancer research and clinical trials.

Expanding Access to Telehealth

During the COVID-19 pandemic, we recognized the value of telehealth. While not a panacea, we believe the availability of appropriate telehealth services enhances the delivery of cancer care and should remain an accessible tool to patients and

¹ <https://ascopubs.org/doi/abs/10.1200/JCO.20.03420>

² <https://www.nimhd.nih.gov/resources/understanding-health-disparities/diversity-and-inclusion-in-clinical-trials.html>

³ <https://www.nimhd.nih.gov/resources/understanding-health-disparities/diversity-and-inclusion-in-clinical-trials.html>

⁴ https://cancerprogressreport.aacr.org/wp-content/uploads/sites/2/2022/06/AACR_CDPR_2022.pdf

providers on a permanent basis. Central to the effective implementation of telehealth access has been the relaxation of geographic restrictions and limitations on originating sites. Allowing patients to see their providers from their homes, regardless of distance, should be permanent Medicare policy. *The Network urges Congress secure beneficiary access to appropriate telehealth services by permanently eliminating Medicare’s geographic and originating site restrictions.*

However, despite the rapid adoption of telehealth in the U.S. since 2020, its implementation in clinical studies remains underutilized. When clinically appropriate, telehealth can significantly support and advance clinical trials. However, barriers exist that hinder organizations from fully leveraging its potential. In rural settings, identifying suitable patients for clinical trials can be challenging. Instead of requiring patients to travel to a clinic to meet with principal investigators, telehealth visits can be used to assess the fit and applicability of patients for trials. This approach can reduce patient burden by minimizing travel time and the need to take time off work or arrange transportation. Additionally, telehealth is ideal for non-treatment visits during a trial, allowing for required assessments without necessitating in-person visits. Licensure requirements are important so that states can ensure that health care providers follow state laws and regulations, and state medical boards can investigate and discipline providers who violate the law. However, we believe that there are scenarios, such as clinical trials, where an expedited pathway to interstate licensure is appropriate. The Federation of State Medical Boards recognizes that “when working on clinical trials that are enabled by telemedicine technologies, physicians should not be precluded from including patients that reside in a state where the physician does not have a license to practice medicine.”⁵

The concept of interstate licensure programs is not new. The Interstate Medical Licensure Compact, created in 2014, establishes a pathway for physicians who are licensed in one of the member states to obtain licensure in other member states.⁶ However, the Compact is constrained by which states choose to participate. The process by which a state can join is lengthy and involves state legislation. There are other compacts, including those for occupational therapy, physical therapy, and emergency medical services personnel, but they face similar challenges.⁷ During the COVID-19 public health emergency, the Centers for Medicare & Medicaid Services (CMS) waived the requirement that health care providers be licensed in the state in which they are providing services if they met certain criteria, including having an equivalent license in another state. *We hope to build on current initiatives and encourage Congress to consider solutions that balance the need to advance and support clinical trials with safeguarding states’ ability to oversee and protect patients.*

Providing Coverage of Genetic Counselor Services in Medicare

Genetic testing is an increasingly important part of comprehensive cancer care. Genetic counselors are highly trained healthcare providers focused on medical genetics and counseling who help patients understand the relationship between genetic contributions to disease and related health implications. While Medicare covers genetic counseling, it does not recognize genetic counselors as providers, making it difficult for community cancer practices to employ genetic counselors and limiting access for patients.

We believe genetic counseling services should be part of an integrated, coordinated care team. *To this end, The Network supports H.R. 3876/ S. 2323, the Access to Genetic Counselor Services Act, which would expand access to genetic counselor services to Medicare beneficiaries.* Expansion of these services will modernize Medicare coverage and strengthen access to life-saving cures.

⁵ <https://www.fsmb.org/siteassets/advocacy/policies/fsmb-workgroup-on-telemedicineapril-2022-final.pdf>

⁶ <https://www.imlcc.org/a-faster-pathway-to-physician-licensure/>

⁷ <https://telehealth.hhs.gov/licensure/licensure-compacts>

Conclusion

On behalf of The US Oncology Network, thank you for the opportunity to provide feedback as you contemplate the next iteration of the 21st Century Cures initiative. We welcome the opportunity the issues outlined above and other critical issues impacting community cancer care with you and your staff. Should you have any questions, please contact Lisa Langenderfer, Sr. Director, Federal Government Relations at Lisa.Langenderfer@mckesson.com.

Sincerely,



Ben Jones
Vice President, Government Relations and Public Policy
The US Oncology Network