CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

November 22, 2022

The Honorable Nancy Pelosi
Speaker
United States House of Representatives
Washington, DC 20515

The Honorable Kevin McCarthy Minority Leader United States House of Representatives Washington, DC 20515 The Honorable Charles Schumer Majority Leader United States Senate Washington, DC 20510

The Honorable Mitch McConnell Minority Leader United States Senate Washington, DC 20510

Dear Speaker Pelosi, Majority Leader Schumer, Minority Leader McCarthy, and Minority Leader McConnell:

The undersigned cancer organizations, representing cancer patients, health care professionals, researchers, and caregivers, are writing to urge action on several important issues as part of end-of-year legislative efforts. We identify below actions that Congress should take to enhance cancer patients' access to quality care and to also improve the quality of life of cancer survivors and their families and friends.

Much progress has been made to improve the outcomes for those diagnosed with cancer, from screening and early detection to improved therapies and systems of care. Efforts to improve outcomes for cancer survivors have enjoyed bipartisan Congressional support, and cancer research and care initiatives have featured strong federal-state and public-private partnerships.

The COVID-19 pandemic has posed significant challenges to cancer screening, diagnosis, treatment, and survivorship care as well as cancer research. Cancer patients and health professionals developed strategies and systems for providing care and conducting research as safely as possible through the pandemic, and federal assistance has been important to those efforts. Unfortunately, the pandemic is not over for the cancer community. Many cancer patients – especially those who are immunocompromised – must still take precautions to protect themselves from COVID exposure and infection. In addition, the effects of the COVID pandemic on cancer care and research are still being felt. Physician practices, hospitals, cancer centers, and all who care for cancer patients still struggle with COVID effects.

The recommendations below are offered on behalf of cancer patients, health care professionals, researchers, and caregivers, in the context of a lingering pandemic.

Relief from Medicare Reimbursement Reductions

Cancer care providers are looking at cuts in Medicare payment in 2023 as a result of a reduction in the Medicare physician fee schedule conversion factor, the impact of budget neutrality requirements, changes in the clinical labor price update that significantly affect payment for certain cancer care services, and the impact of sequestration. The payment reductions will affect all cancer care providers, but the impact will be variable. For some practices, the impact will be substantial. We are concerned that the payment changes will be significant enough to affect the delivery of cancer care in many areas. Those locations that are already medically underserved will be most likely to suffer significant adverse effects from the payment cuts, but no region of the country and few patients will be unaffected by these changes.

These payment cuts come as the COVID-19 pandemic is still being felt by those diagnosed with cancer and those providing cancer care and engaged in research. Now is not the time to expose the cancer community to more disruptions, which may affect cancer diagnosis, treatment, and outcomes. The impact on the cuts may be especially severe for low-income, minority, and rural cancer patients. Congressional intervention to stop the cuts in physician payment is imperative.

Prior Authorization Reform

We urge Congress to act to set standards for prior authorization in Medicare Advantage plans to protect patient access to necessary care. Currently, Medicare Advantage enrollees experience delays in care because of prior authorization processes, and the Inspector General of the Department of Health and Human Services also reports denials of care to Medicare Advantage patients. Clear standards for prior authorization would help address these delays and denials faced by patients. These standards would also reduce the burden placed on providers seeking authorization for care for their patients. Congress has signaled its support for clear prior authorization standards by House enactment of HR 3173, the Improving Seniors Timely Access to Care Act. More than 50 Senators are cosponsoring the Senate companion bill, S. 3018. Congress has already signaled strong support for prior authorization reform. Now, Congress should advance the legislation in the end-of-year session.

Fiscal Year 2023 Appropriations for Cancer Programs and COVID-19 Response

As we have discussed above, a strong federal role in research has been critical to our progress in cancer research and care. At no time has this been truer than during the COVID-19 pandemic. We urge Congress to continue this commitment by approving at least the House Appropriations Committee-passed appropriations for the National Institutes of Health. This level of funding is \$47.459 billion.

We recommend that Congress approve \$7.76 billion for the National Cancer Institute, which is the professional judgment budget for the institute. This exceeds the House Appropriations Committee-approved level of \$7.379 billion, which we acknowledge signals a strong ongoing commitment to NCI.

The Division of Cancer Prevention and Control at the Centers for Disease Control and Prevention should be provided appropriations of \$462.6 million, which would permit critical increases in

funding for key cancer programs within the division. The recommendations above are consistent with those of cancer advocates across the nation.

We also support additional funding for the COVID-19 response. Access to COVID-19 tests, vaccines, and therapeutics should be protected for all, but in supporting additional COVID-19 funding, we underscore the critical needs of those cancer patients who are immunocompromised. For these patients, the COVID-19 pandemic is not over. They require access to tests, vaccines, and therapeutics, and those who treat them need resources to create the safest possible setting to provide care. The cancer research enterprise is also still suffering from pandemic-associated burdens, and additional resources will help researchers address pandemic-related issues.

Telehealth Flexibilities

We recommend that Congress make permanent certain flexibilities that the Consolidated Appropriations Act, 2022, extended until 151 days after the end of the COVID-19 public health emergency. These flexibilities include the waiver of the geographic and originating site restrictions and allowing certain services to be furnished by audio-only telecommunications systems. We appreciate the previous action to extend flexibilities until 151 days after the end of the public health emergency. However, health care providers and patients would be served well by the certainty that comes with permanent grant of the flexibilities.

We also encourage the Centers for Medicare and Medicaid Services (CMS) to make permanent the temporary telehealth codes that are available until 151 days after the public health emergency expiration.

Policy Provisions Associated with FDA User Fee Act

We encourage Congress to act on important legislative provisions that had been negotiated in a bipartisan fashion as provisions of the Food and Drug Administration user fee reauthorization package but were dropped from the package earlier this fall. Of particular interest to us are the clinical trial diversity provisions and the accelerated approval provisions.

Encouraging Clinical Trial Diversity

We support clinical trial diversity legislation that would: 1) encourage the Food and Drug Administration to provide guidance on clinical trial designs that promote diversity in participation; 2) permit the Department of Health and Human Services to engage in education and outreach to encourage clinical trial diversity; and 3) permit sponsors to provide patient remuneration and digital health technologies that will facilitate clinical trial participation by diverse populations.

We encourage Congress to advance such provisions in its year-end package.

Providing Predictability Regarding the Accelerated Approval Pathway

The accelerated approval pathway has been critical to expediting therapies to cancer patients. Those patients who are treated with drugs approved on an accelerated basis, their cancer care teams, and sponsors developing new cancer drugs would benefit from clarity about the confirmatory trial requirements for drugs approved according to the accelerated approval pathway. If there is greater clarity, patients and providers will understand the benefits of drugs, and sponsors will understand the regulatory requirements at the beginning of the development process. We urge Congress to act on the accelerated approval provisions that the team negotiating user fee legislation considered earlier this year. Taking these actions will strengthen the accelerated approval pathway and guarantee its continued use for the benefit of patients in need of new therapies.

Lymphedema Treatment Act

The Lymphedema Treatment Act (HR 3630 and S 1315) would provide Medicare coverage of physician-prescribed lymphedema compression treatment items. These compression garments and related items provide benefit to cancer patients who develop lymphedema (swelling of arms or legs due to lymphatic system blockage) because of their cancer treatment.

The House of Representatives passed this legislation on November 17, 2022. The bill has been sent to the Senate, where there are 74 cosponsors of the bill. It is clear that Congress supports this important legislation, and you should ensure final action on the bill by including it in the year-end package. With this action, you can guarantee the benefits of lymphedema treatment items are provided to patients who struggle with this serious treatment side effect.

Metastatic Breast Cancer Access to Care Act

More than 168,000 Americans are living with metastatic breast cancer. Many of these patients are disabled by their disease, unable to work, and in urgent need of disability and health insurance benefits. Sadly, many of them will not survive the five-month waiting period for Social Security Disability Insurance (SSDI) benefits and the 24-month waiting period for Medicare coverage.

Many in Congress have acknowledged the plight of metastatic breast cancer patients by cosponsoring the Metastatic Breast Cancer Access to Care Act (HR 3183/S 1312), which would waive the SSDI and Medicare waiting periods. There are currently 236 House cosponsors and 28 Senate cosponsors of this legislation.

We urge Congress to advance this legislation for the benefit of metastatic breast cancer patients. The undersigned include organizations and advocates representing survivors of many forms of cancer in addition to metastatic breast cancer. Some of them face the same situation as those with metastatic breast cancer – that is, they will not survive the length of the SSDI and Medicare waiting periods. We urge you to act on the Metastatic Breast Cancer Access to Care Act now, and we will be back soon to encourage equitable treatment of other cancer patients in comparable situations.

Cancer Drug Parity Act

Cancer drug therapy may be delivered to patients through physician-administered drugs or oral, self-administered drugs. The choice of therapy should be driven by evidence, and the decision regarding the appropriate therapy should be made by patients and their physicians. Unfortunately, the cost-sharing standards for physician-administered and oral, self-administered drugs are not always comparable. Patients may find that the cost-sharing for oral drugs is prohibitive, and as a result they may default to a therapy that is perhaps not the best choice but has the more manageable cost-sharing responsibility.

We urge Congress to include the Cancer Drug Parity Act in its end-of-year package. This bill (HR 4385/S 3080) would require federally regulated group health plans to have comparable cost-sharing requirements for oral, self-administered and physician-administered drugs. Under this standard, patients and their physicians will make decisions that are driven by medical evidence and not decisions that are driven by cost-sharing.

Thank you for your attention to this list of year-end priorities for cancer patients, health professionals, researchers, and caregivers. We realize that this list is of some length and complexity. However, with regard to many of these initiatives, Congress has already signaled strong bipartisan support. Yet these solutions to critical and time-sensitive problems facing cancer patients have not advanced. We urge you to take advantage of the year-end legislative session to attend to these matters and to advance quality health care for cancer patients.

Sincerely,

Cancer Leadership Council

Academy of Oncology Nurse & Patient Navigators
American Society for Radiation Oncology
CancerCare
Children's Cancer Cause
College of American Pathologists
Family Reach
Fight Colorectal Cancer
Hematology/Oncology Pharmacy Association
International Myeloma Foundation
LUNGevity Foundation
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
Ovarian Cancer Research Alliance
Prevent Cancer Foundation
Susan G. Komen