CANCER LEADERSHIP COUNCIL

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

June 1, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: CMS-1744-IFC, Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

Dear Administrator Verma:

The undersigned organizations representing cancer patients, health care professionals, and researchers are writing to commend the Centers for Medicare & Medicaid Services (CMS) for providing flexibilities to health care professionals, institutions, and patients so that they may provide and receive high quality health care safely during the COVID—19 emergency. We offer advice about some additional steps that could be taken during the public health emergency and commit to providing updates regarding the impact of these flexibilities on cancer care.

Telehealth

We applaud the actions by CMS to improve access to telehealth services during the COVID-19 public health emergency, so that patients can receive care in their homes and minimize their risk of contracting coronavirus. In the weeks since the interim final rule was published, cancer providers and patients alike have embraced the potential of telehealth. We stress that both patient and provider play a role in this new method of care. In our brief experience, they are offering each other advice about the telehealth experience, and we believe over time that cancer providers and patients can offer advice to the agency about telehealth delivery, quality of care, and constant quality improvement.

The agency enhanced access to telehealth by identifying several services that can be provided through telehealth and by offering clear advice about billing for those services. Importantly, CMS advised that services provided through telehealth may be paid the same as if the service were provided in the office of outpatient setting. In addition, the IFR included permission for telehealth services to be provided by phone, for an audio-only visit.

In the weeks following the publication of the IFR during which cancer care professionals have provided telehealth services, we have learned that older Americans with limited access to

technology may only be able to receive phone-only telehealth services. Unfortunately, the payment for audio-only visits has been limited and did not permit reimbursement of the provider as if the service were provided in the office or outpatient setting.

We have been concerned that access to telehealth services for older Americans might be limited due to payment issues, and we are pleased that CMS acted on April 30, 2020, to increase payment for audio-only telehealth. With that change and additional changes expanding those professionals who may provide telehealth, CMS is responding promptly as issues arise in the delivery of and payment for telehealth. This approach ensures that telehealth can help to protect access to care during the COVID-19 public health emergency.

In the initial weeks of expanded use of telehealth services, we have identified some barriers to receiving the full advantage of telehealth. A major obstacle is the lack of real interoperability of medical records. Gaps in interoperability have affected cancer patients who are receiving telehealth services in several ways. A typical problem is the inability to obtain and share the results of scans so that patient and provider can participate in a telehealth visit for review of those results. Patients have reported to us that they need to leave home to obtain test results from one provider to share with other provider, an effort that fundamentally undermines the advantages of telehealth.

In addition to receiving these early reports about telehealth advantages and obstacles, the cancer community is listening carefully to patients and providers and is engaged in a real-time dialogue about achieving and maintaining quality in telehealth. Both health care professionals and patients are part of this effort, and we will share additional results of the cancer community's training and learning. However, we recommend that CMS play a role in provider education, patient communication, and quality assurance and improvement initiatives related to telehealth. We believe we and other patient and provider communities could assist in such efforts.

Direct Supervision Changes to Permit Home Infusion

The interim final rule would make changes to Medicare direct supervision requirements so that administration of Part B drugs that are physician-administered could be delivered instead by home infusion. In explaining the reasons for its actions to permit home infusion of Part B drugs with changes in the direct supervision requirements, the agency offered some scenarios that might occur because of the COVID-19 public health emergency. CMS suggested that patients "may lose access to the provision" of a Part B drug because the physician who regularly supervises the administration of that drug may be isolated for the purpose of minimizing exposure risks. The agency also described a situation in which the patient might need to be "isolated for purposes of exposure risk based on presumed or confirmed COVID-19 infection."

In the weeks that we have been confronting the COVID-19 crisis, oncology providers have developed and publicized guidelines for the delivery of cancer care during the public health emergency. For some cancer patients, due to their diagnosis or recommended course of therapy, treatment may be delayed during the public health emergency. For some, there may be a concern that their disease or treatment will increase their risk of contracting COVID-19. For others, treatment is recommended to proceed. In addition to providing guidance about treatment timing during this crisis, oncology providers have established procedures and

processes in their offices to minimize risk of COVID-19 exposure to patients and professional staff and to maintain high quality cancer drug administration. As a result, patients are reporting that major interruptions in care are not occurring, unless their therapy (surgery, drug therapy, or radiation therapy) is being delayed according to COVID-19-related guidelines.

Many cancer patients have voiced concerns about receiving Part B drugs at home. Although patients have embraced the potential for receiving telehealth services, they have distinguished the delivery of telehealth services from the delivery of Part B drugs. Patients want assurances, if their drugs are administered by home infusion, that the side effects of treatment are managed appropriately and as they would be in the physician office or outpatient clinic. Patients also want to understand that the standards for safe handling of cancer drugs can be honored in their homes and that they, their families, and the professionals handling the drugs will be safe.

Cancer patients have also asked very practical questions about home infusion of cancer drugs. Where in the home will the infusion take place? Because many patients are staying at home during the coronavirus public health emergency, space may be at a premium and patients want to be sure that the infusion can take place safely and apart from their family members, including children. Finally, patients are expressing misgivings about the fact that health care providers will be coming into their homes at the time of the COVID-19 crisis, perhaps presenting a risk to them and their families. There also appears to be a continuing problem with the availability of personal protective equipment, and this could be an obstacle to the safe provision of home infusion services. As we noted above, there are critical differences between telehealth, which is not accompanied by these risks, and home infusion.

We understand that, despite the reservations about home infusion among some patients, there may be circumstances where home infusion is a reasonable choice for a patient. We recommend that patients and their physicians discuss the benefits and risks of home infusion of cancer drugs and that the questions above related to safety and convenience be answered to the patient's satisfaction.

Cancer patients understand that the provisions of the interim final rule that would permit, or even encourage, home infusion were spurred by concerns about access to Part B drugs. Fortunately, oncology practices have established systems for managing the care of their patients in the safest possible way, and access to Part B drugs has by and large been protected.

We urge that decisions about home infusion be made on an individual basis only after a careful consideration of risks and benefits by patient and health care professional. In addition, we urge that the use of home infusion for Part B cancer drugs be subject to additional analysis and discussion after the public health emergency and if continuation of the flexibility related to physician supervision of drug administration is considered.

Adapting to the COVID Pandemic and Beyond

Although oncology practices of all sizes and types are adapting to the COVID-19 public health emergency to protect patient access to care, practices report significant practice, personal, and financial strains. Adapting to telehealth, even though a positive for protecting access to care, has created some strain on practices. Modifications of processes and procedures in practices result in seeing fewer patients, and of course some patients are being advised to delay care for

reasons related to coronavirus. Oncology practices are already "different" than they were before the public health emergency, and those differences are creating stress for many. We appreciate CMS' efforts to support oncology practices financially during this time of need and encourage the Agency to continue taking steps to shore up oncology clinics to preserve cancer patient access to care.

Many patients, providers, and health care reformers are looking for the silver lining in the public health emergency and see the opportunity for reform and rejuvenation of health care – including cancer care – as the COVID-19 emergency lessens in its urgency. CMS has shown its ability to move quickly and creatively in its regulatory actions to provide flexibility to health care providers and patients during the COVID-19 emergency. We urge you to bring that same attitude to reforms after COVID and to collaborate not only with providers but also with patients and patient advocates to strengthen our health care system after the coronavirus crisis.

Sincerely,

Cancer Leadership Council

American Society for Radiation Oncology
Association for Clinical Oncology
Children's Cancer Cause
Fight Colorectal Cancer
LUNGevity Foundation
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
Ovarian Cancer Research Alliance
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Susan G. Komen

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