May 18, 2020

Electronically submitted to: http://www.regulations.gov

The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1744-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

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

Dear Administrator Verma:

On behalf of the Board of Directors of the Community Oncology Alliance (“COA”), I am submitting this comment letter to the Centers for Medicare & Medicaid Services (“CMS”) in response to the Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Interim Final Rule (CMS-1744-IFC) (“Interim Final Rule”).

As you know, COA is an organization that is dedicated to advocating for the complex care and access needs of patients with cancer and the community oncology practices that serve them. COA is the only nonprofit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. COA’s mission is to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities where they live and work. For 17 years, COA has built a national grassroots network of community oncology practices to advocate for public policies to support patients with cancer.

COA appreciates CMS’ efforts to allow flexibility to providers during the COVID-19 (novel coronavirus) pandemic as essential health care providers and care settings dramatically adjust operations in order to continue to provide vital medical care to patients during this turbulent time. Independent, community oncology practices have quickly adapted and are taking extreme measures to keep their facilities and providers COVID-19 free so that their patients in active cancer treatment can be assured of a safe medical treatment environment. This includes leveraging and expanding the use of telehealth services to monitor patients and ensuring that only those that are in urgent need of treatment physically come into the practice. As such, COA acknowledges and commends CMS’ decision under your leadership in the Interim Final Rule to amend regulations to provide flexibility for the increased use and reimbursement of telehealth services as a replacement for face-to-face visits, when deemed medically appropriate.

However, COA is concerned that some of the flexibilities included in the Interim Final Rule, while suitable for other therapeutic areas, are inappropriate for cancer care. Specifically, the additional flexibilities for patients to receive in-home infusions, especially by home health agencies, in order to minimize the risk of exposure to COVID-19. Although COA appreciates CMS’ work to address challenges faced by providers due to COVID-19, COA fundamentally
opposes home infusion of chemotherapy, cancer immunotherapy, and cancer treatment supportive
drugs, especially by untrained nurses, because of serious patient safety concerns.

The widespread implementation of home infusion for cancer treatment would have a major impact on
patient safety and continuity of care, as a patient’s cancer treatments are ever-changing and require
modifications on a routine basis. Modern cancer treatments are very complex regimens and involve
combinations that can include chemotherapy, biologics, immunotherapy, and supportive agents (e.g.,
growth factors), and necessitate face-to-face, high-touch evaluations and re-evaluations with each cycle of
treatment for safety to address adverse side effects, and to determine the efficacy or lack thereof.

Given the complexities of cancer treatment, there is significant concern that home infusion of cancer drugs
will be administered by a provider who may not recognize and be prepared to treat any adverse reactions
that may occur as a common part of an infusion of cancer treatment. Many of the side effects caused by
cancer treatment can have a rapid, unpredictable onset that places patients in incredible jeopardy and can
even be life-threatening. These significant side effects need to be managed expertly for patient safety and
comfort. As such, it makes little sense that a patient’s visit to receive infusion cancer treatment would be
separated from a specialized treatment setting under the direction of their physician and a team of trained
oncology nurses into an unsupervised home environment.

I want to underscore that the complexity of oncology treatment necessitates the administration of oncology
infusion therapies by a specialized oncology nurse who is specifically trained to administer the dangerous
medications used in cancer chemotherapy and immunotherapy and to observe, identify, and treat any
adverse reactions. Home infusion negates the benefits of the expertise and team approach to cancer care,
which are the hallmarks of community oncology, within facilities specifically designed for safe and
effective cancer drug infusions. In an outpatient infusion center setting, this expertly trained and
experienced care team has at hand many options to address any adverse reactions and ensure patient safety.

For these reasons, and more, the majority of oncologists conclude that home infusion is not appropriate or
safe for patients with cancer.

COA notes that there are other medical specialties and the diseases they treat where the infusion of Medicare
Part B drugs at home may be reasonable during the COVID-19 pandemic. As a result, COA currently limits
this position and opposition to the home infusion of cancer treatments. I also note that home health agencies
are a vital part of medical care delivery, even related to ancillary aspects of cancer care. However, this does
not include the administration of cancer drugs under an oncologist’s supervision.

Community oncology practices continue to provide high-quality, affordable, and accessible cancer care to
the communities they serve, despite challenges faced in the extraordinary circumstances of this COVID-19
crisis. As hospitals are overwhelmed with COVID-19, independent community oncology practices are on
the frontlines of treating cancer patients, keeping them COVID-19 free and out of the hospital.

Given the outstanding circumstances spanning the realm of health care delivery, we thank CMS for quickly
taking appropriate actions to help community oncologists continue to provide care in the context of this
public health emergency. However, we also urge CMS to strongly consider the unique characteristics of
cancer treatment in its efforts to expand home infusion. We would be happy to discuss further and assist
CMS in any way possible.

Sincerely,

Michael Diaz, MD
President

COMMUNITY ONCOLOGY ALLIANCE