June 1, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1744-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted Electronically at www.regulations.gov

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

Dear Administrator Verma,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (CMS-1744-IFC) interim final rule published in the Federal Register on April 6, 2020.

ASCO is a national organization representing more than 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans, including Medicare beneficiaries and Medicaid enrollees.

ASCO recognizes the Centers for Medicare and Medicaid Services (CMS) for the tremendous effort and work the agency has done to promote efficiency and streamline processes for healthcare providers during the COVID-19 pandemic and public health emergency. The course of action CMS has taken to expand the bandwidth of our healthcare system has allowed practitioners to serve as many patients as possible during the public health emergency (PHE). We appreciate the steps CMS has taken on a temporary basis to promote telehealth through relaxed restrictions and increased flexibility, to reduce administrative burden, to increase hospital capacity, and to expand the healthcare workforce.

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ASCO supports the flexibilities CMS has implemented to ensure telehealth is available to more practitioners and patients during the Public Health Emergency (PHE), and we urge CMS to consider extending the expanded telehealth policies after the expiration of the PHE.
During a time when staying home is crucial to the health and wellbeing of all Americans, ASCO applauds CMS for taking swift action to ensure that all Medicare beneficiaries have access to telehealth services and that practitioners have the flexibility to provide these services during the PHE. Telehealth is also a necessary means to keep physicians and other healthcare providers safe and healthy. Perhaps more than ever, patients with cancer and survivors need communication and care from their healthcare team. However, for many patients, especially those with compromised immune systems, it is essential they stay at home to remain as healthy as possible. By implementing telehealth regulatory changes and flexibilities, CMS has enabled these patients to remain in their homes while still receiving high quality care from their health care team.

ASCO appreciates CMS’ implementation of the many provisions that increase patient access to telehealth services, including waiving the originating site requirement which allows all Medicare beneficiaries, regardless of geography, to receive telehealth services in their own homes, and by adding additional services to the CMS list of covered telehealth codes. We thank CMS for expanding access to telehealth, virtual check-ins, and e-visits to now include new patients in addition to established patients. Patients may develop new conditions requiring a visit with a specialty provider during the pandemic and it is important that these patients remain able to access necessary services for new conditions.

ASCO commends CMS for regulations and flexibilities that support practitioner use of telehealth services. To help ensure that practices remain financially stable and to maintain relativity in the Medicare Physician Fee Schedule (PFS), CMS issued billing guidance addressing the payment differential through an updated place of service code policy. At the start of the PHE when our members began rapidly adopting telehealth, we heard numerous concerns from our members regarding inadequate reimbursement of telehealth, especially as in-person visits were not an option. We appreciate the updated policy to reimburse telehealth as if the visit had been conducted in person (e.g. office-based physicians being reimbursed at the non-facility rate), thus enabling physicians to utilize telehealth for appropriate patients. ASCO also appreciates that CMS has established payment equity for audio-only telehealth visits with office visits provided via audio-visual technology. This was a critical flexibility since many patients were not able to communicate with their physicians through audio-visual technology.

Another provision that may help to promote telehealth is the flexibility providers have to waive or reduce cost sharing, which limits patients’ out-of-pocket spending. Additionally, CMS covers the guidance the Office of Civil Rights released stating that physicians and patients may use their smart phones with popular non-public-facing applications such as Zoom, Skype, and Google to provide and receive telehealth services, again enabling a greater proportion of the population to take advantage of these services.

Through these comprehensive and extensive changes in telehealth policy leading to increased adoption, CMS has underscored the profound impact telehealth services can have on patients, practitioners, and our overall healthcare system. We agree that the “genie is out of the bottle” and it now becomes important to assure that post-pandemic payment policy for telehealth will preserve policies that support its expanded role in the care of patients with cancer. We recognize that some of the flexibilities and expansions may require statutory changes, and we encourage CMS to work collaboratively with stakeholders in seeking congressional adoption of those changes. For those policies which may be adopted by changes in regulations or sub-regulatory guidance, we urge CMS to adopt such changes administratively allowing for stakeholder collaboration.
We expect and hope that data we and other organizations are collecting will provide insight about the impact of telehealth services on health outcomes, the quality and safety of services provided, and patient access, especially within the cancer population. As these data become available, we look forward to working with CMS to make permanent expanded telehealth policies that will ensure greater access to all Medicare beneficiaries beyond the expiration of the PHE with patient safety and quality of care the foremost consideration.

**ASCO appreciates CMS’ efforts to reduce administrative burden for physicians; specifically, we appreciate CMS’ announcement of the MIPS data reporting delay and increased availability of hardship exemptions.**

ASCO thanks CMS for recognizing that during this public health crisis it may be challenging or impossible for physicians, groups, and virtual groups to meet the data submission deadline due to circumstances beyond their control. We appreciate the flexibilities provided to MIPS eligible and clinicians and group practices to choose to submit data or to apply for—and in some circumstances, receive automatically—a hardship exemption.

**ASCO appreciates the implementation of Medicare Part D flexibilities intended to ensure adequate supplies of medications for patients.**

Now, more than ever, it is critical that patients maintain an adequate medication supply. The ASCO appreciates the relaxation of “refill-too-soon” edits and the ability for patients to obtain the maximum extended day supply available under their plan to allow an uninterrupted supply of critical medications. This is a critical support at a time when disruptions to routine care may be expected.

**ASCO has significant concerns about the safety of home infusion for chemotherapy drugs and does not support its use, unless there are extraordinary circumstances and a treating physician—in consultation with the patient—has determined it is the most appropriate alternative.**

In an effort to reduce COVID-19 exposure risks for the beneficiary and the health care provider, CMS has offered a temporary provision in which physicians may enter into contracts with home health agencies or a qualified infusion supplier to provide part B drug infusion services for patients in their home. Supervision of the service may be performed through audio-visual communications, and payment is made to the billing practitioner, who then makes the appropriate payment to the contracted entity. The payment is made in accordance with the Medicare Physician Fee Schedule and would not be considered a home health service under the Medicare home health benefit. CMS acknowledges that this flexibility in supervision does not change the underlying payment or coverage policies related to Part B drugs and the agency seeks comment on whether there should be any guardrails and what risk this policy might introduce for beneficiaries while reducing risk of COVID-19 spread.

ASCO appreciates the intent of CMS to improve access by expanding the scope of home infusion services and associated providers. We understand this may be an option in exceptional circumstances and as a result of informed, shared decision making between the physician and patient. However, while such an expansion may be appropriate for patients in certain disease settings, ASCO does not generally support
such an expansion of home infusion to include chemotherapy services. Our members have expressed concerns, primarily around patient safety, but also the feasibility for practices to deploy clinic staff in this way. Specifically, we have heard concerns from practices about:

- Patients’ ability to obtain adequate medical evaluation prior to administration of medication
- Managing adverse reactions that may occur outside of a medical facility
- Managing a high volume of complex infusions with limited or reduced staff
- Safely transporting hazardous medications and related equipment
- Ensuring staff and patients have proper personal protective equipment

Oncologists are making difficult decisions to delay or adjust care during this crisis. Despite a desire to mitigate this, patient safety must continue to be the first priority in making these decisions.

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We appreciate the opportunity to comment on the Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency interim final rule. Please contact Gina Baxter (gina.baxter@asco.org) or Karen Hagerty (karen.hagerty@asco.org) with any questions or for further information.

Sincerely,

Monica Bertagnolli, MD, FACS, FASCO
Chair of the Board
Association for Clinical Oncology