October 27, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3401-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted Electronically at www.regulations.gov

Re: Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program

Dear Administrator Verma,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the *Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (CMS-3401-IFC)* interim final rule with comment period published in the Federal Register on September 2, 2020.

ASCO is a national organization representing nearly 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.

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ASCO thanks CMS for including submission of patient data to a COVID-19 clinical data registry for participation in Improvement Activity IA_ERP_3 and for extending this through the 2021 performance period.

In the third COVID-19 interim final rule, CMS is expanding improvement activity (IA) IA_ERP_3 to include clinicians participating in the care of a patient

diagnosed with COVID-19 and simultaneously submitting their patient data to a clinical data registry for research. CMS clarifies that to receive credit for this IA a MIPS eligible clinician or group must: (1) participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; **OR** (2) care for patients diagnosed with COVID-19 and submit relevant data to a clinical data registry for COVID-19 research. Additionally, CMS will extend reporting on this IA through the end of the CY2021 performance year.

ASCO supports the actions CMS is taking to include clinicians caring for COVID positive patients submitting data to a clinical data registry to report on this improvement activity. ASCO established a COVID-19 registry to help the entire cancer community learn about the pattern of symptoms and severity of COVID-19 among patients with cancer. The ASCO Registry is designed to collect both baseline and follow-up data on how the disease impacts cancer care and cancer patient outcomes during the COVID-19 pandemic – up to 12 months after a patient's COVID-19 diagnosis. Cancer patients with a COVID diagnosis are a special subgroup of individuals whose clinical condition need to be understood to ensure effective treatment protocols and positive health outcomes. ASCO thanks CMS for confirming that ASCO's Survey on COVID-19 in Oncology Registry is an acceptable registry for the attestation of this highly-weighted practice improvement activity.

ASCO supports the extension of this IA into 2021. On October 2, the Department of Health and Human Services (HHS) Secretary renewed the Public Health Emergency (PHE) effective October 23, extending the PHE into 2021. Furthermore, it is likely that this improvement activity will remain relevant throughout the next year and possibly beyond, given the unknowns around how long the virus will persist in the community and possible long-term effects stemming from infection. Given the impact the coronavirus has on caring for cancer patients, it is imperative that oncologists have the opportunity to submit meaningful improvement activity data that reflect real-world events and that are of value to patients and clinicians.

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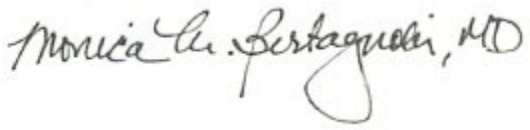
We appreciate the opportunity to comment on the *Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency* interim final rule. Please contact Gina Baxter (gina.baxter@asco.org) or Karen Hagerty (karen.hagerty@asco.org) with any questions or for further information.

Sincerely,



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