ASCO®
ASSOCIATION FOR CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

December 23, 2020

Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington DC 20201

Dear Secretary Azar,

The nature of the COVID-19 pandemic and resulting public health emergency required unprecedented response and flexibility across the health care sector to avoid disruption in care delivery, continuity of research activities and to ensure the protection and safety of patients and health care workers. Additionally, in the face of economic pressures created by the pandemic, practices, health care facilities and institutions- functioning as employers and businesses- required similar response and flexibility from state and federal policymakers. The Association for Clinical Oncology (ASCO) appreciates the opportunity to provide feedback on The Agency's Request for Information on Regulatory Relief Efforts to support Economic Recovery.

ASCO is a national organization representing more than 45,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest-quality patient care, our members are committed to ensuring that evidence-based practice for the prevention, diagnosis, and treatment of cancer are available to all Americans. ASCO supports major quality initiatives that enhance performance measurement and improvement, clinical practice guidelines, big data analytics, and the value of cancer care.

Cancer patients and survivors are one of the most vulnerable patient populations, and face increased risk related to COVID-19. Prior to the public health emergency, certain longstanding policies, care delivery practices and research procedures posed barriers to the efficient delivery of care and effective clinical research. During the pandemic, temporary regulatory relief offered by the Agency on some of those same policies, coupled with the nimbleness of the health care sector, proved beneficial to patients and enabled the nation's health care system to continue to operate safely during the time of crisis. ASCO commends the Administration and the Department of Health and Human Services (HHS) for recognizing the need to modify existing policies that would have significantly affected care for cancer patients. Like many organizations, ASCO has taken the opportunity to evaluate whether the

changes in care delivery and research prompted by the pandemic could inform new approaches to delivery of high quality, high value care and research moving forward.

ASCO recently published the *Road to Recovery Report: Learning from the COVID-19 Experience to Improve Clinical Research and Cancer Care*, which outlines recommendations based on lessons learned during the pandemic. Proposed actions and policies aim to make cancer care delivery and research opportunities more accessible and equitable for patients in every community. With these recommendations, ASCO intends to address long-standing cancer care disparities that have been highlighted by the pandemic. To achieve these goals, certain regulatory flexibilities driven by the pandemic may need to be permanent—or at least extended for a minimum of 24 months following expiration of the PHE. This would enable cancer patients to continue access to life-saving treatments for their disease, for providers to continue delivery of high-quality cancer care, and all in the cancer community to benefit from protections against personal and economic the impacts COVID-19.

Part I: Cancer care delivery – Policies and regulatory action must build on strategies that have helped to meet patients' most urgent needs in the worst of the pandemic. Specifically:

Increased access to and equity of care – by making expanded coverage for telemedicine permanent; preventing Medicaid cuts; ensuring accessible, affordable and comprehensive insurance plans, and preventing other threats to patients' health coverage; enhancing grants and other support for oncology practices in underserved communities; and sustaining federal safety net programs

Protecting patient safety – for example, by creating new chemotherapy infection control standards that account for viral threats like the novel coronavirus; ensuring reliable access to personal protective equipment (PPE) and future COVID vaccines; and limiting home infusion of potentially risky chemotherapy to exceptional circumstances

Supporting patient and provider well-being – by expanding access to behavioral health care and psychosocial support for patients; and enhancing training and support for care teams, which have been disrupted by staffing changes and burnout in the face of the pandemic.

Additional recommendations related to Cancer Care Delivery can be found in the *Road to Recovery Report.*[1]

Below, ASCO outlines recommendations for regulatory policies implemented temporarily during the PHE to be permanently implemented.

A. **Telemedicine - Generally, ASCO supports the flexibility CMS has implemented to ensure telemedicine is available to more practitioners and patients during the COVID-19 PHE, and we urge CMS to extend those expanded telemedicine policies after the expiration of the PHE. In addition to Medicare beneficiaries, we support the permanent implementation of these policies for Medicare Advantage as well as Medicaid enrollees.**
   4 – Notification of Enforcement Discretion for Telehealth Remote Communications

[1] https://ascopubs.org/doi/full/10.1200/JCO.20.02953

ASCO supports the use of HIPAA compliant audio/visual technology after the expiration of the PHE.

Privacy and data security issues and concerns related to health care information technology (HIT) have been key barriers to adoption of telemedicine and impact the confidence of patients and practitioners using these tools. As the use of telemedicine continues to increase, it will necessarily generate large quantities of personal health information and data, highlighting the need for data protection. Clear direction on the application of HIPAA requirements and necessary liability protections for providers is needed.[2]

111 – Communication Technology Based Services (CTBS); and

112 – Direct Supervision by Interactive Telecommunications Technology

ASCO supports the permanent implementation of policies allowing the provision and reimbursement of CTBS for new and established patients. Additionally, ASCO supports permanent implementation of provisions allowing direct supervision through interactive telecommunications technology. However, ASCO does not support direct supervision through interactive telecommunications technology in the context of home infusion for anti-cancer therapies outside of the PHE.

Mitigating the need for an in-person visit is critical for cancer patients, who are at an increased risk during the PHE, but may also experience similar risks because of compromised immune systems during cancer treatment. Allowing both new and established patients use of CTBS to access necessary care during brief communication mitigates the need for an in-person visit that could represent an exposure risk. Granting physicians flexibility to provide clinically appropriate and high-quality care to these beneficiaries via telemedicine can help keep these vulnerable patients in their homes, reducing unnecessary exposure to all illnesses, not just COVID-19.

Regarding direct supervision for home infusion of anti-cancer therapies, ASCO believes that guardrails need to be in place as this temporary policy introduces the potential for risk.[3] There is a paucity of evidence directly comparing the safety of chemotherapy infusions in the home with treatments delivered in outpatient settings. Most of the literature examines home infusion in general, which is of limited utility given the toxicity and hazardous materials specific to chemotherapy. However, multiple criteria in ASCO's existing safety standards may be difficult to satisfy in the home infusion context. For example, safety principles emphasize using more than one practitioner to verify and document patient name, drug name, dosage, infusion volume, route/rate of administration, etc., to minimize errors and prevent patient harm. Within a health care setting additional trained staff are available for such verification. In the home infusion setting, these verifications need to be performed virtually and with multiple forms of identification, as sending multiple health workers to supervise home infusions may not be practical or feasible. Most importantly, certain adverse events that may quickly escalate and become life-threatening emergencies may not be able to be safely resolved in the patient's home.[4]

[2] https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020-ASCO-Interim-Position-Statement-Telemedicine-FINAL.pdf
[3] https://www.asco.org/sites/new-www.asco.org/files/content-files/2020-COVID19-IFC1-Comment-Letter.pdf
[4] https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020_Home-Infusion-Position-Statement.pdf

In addition to safety concerns outlined above, there are workforce and reimbursement issues that present challenges with home infusion of anticancer therapy. An oncology nurse in a clinical setting can safely supervise infusion of multiple patients at once, compared to single-patient oversight in the home setting. There may therefore be insufficient oncology nursing expertise to widely adopt home infusion and substituting generalist infusion nurses does not provide the same level of patient safety.[5]

113 – Telephone Evaluation and Management (E/M) Services Codes

ASCO supports the implementation of permanent policies to allow Telephone Evaluation and Management Services. ASCO encourages Policymakers and payers at the national and state levels to ensure robust, adequate reimbursement and coverage of telemedicine for care delivery via audio and/or audio and visual formats regardless of site of service.[6]

State and federal policymakers should make permanent coverage and reimbursement for audio-visual and when appropriate, audio-only services and continue to expand coverage for all modes of delivery of telemedicine. The lack of broadband and/or access to technology for both patients and physicians will not be limited to the time during the PHE; therefore, we urge that all respective agencies extend these regulatory changes beyond the PHE. Patient populations who lack computer skills or broadband access could potentially benefit especially from audio-only services.[7]

ASCO is committed to supporting efforts that ensure oncologists have the resources they need to provide high-quality cancer care regardless of where that care is delivered; therefore, we believe CMS should cover and reimburse audio-only services. Analysis of data from ASCO practices shows that of all services provided through technology-based communications from mid-March through mid-June, audio-only visits make up 35%-50% of these technology-based visits; virtual check-ins made up less than 1%.[8] Cancer patients are relying heavily on audio-only E/M services and need CMS to ensure they have access to the care they need.

ASCO's Policy Statement on Cancer Disparities and Health Equity commits ASCO to "support and promote policies, systems, environments, and practices to address persistent barriers to equitable receipt of high-quality cancer care across the care continuum."[9] CMS should work to promote health equity through encouraging the use of telemedicine in all care settings, including but not limited to rural and safety net providers. CMS should cover and reimburse audio-only services in order to prevent the unintentional exacerbation of health inequities.

While we agree with the agency that telehealth platforms incorporating both audio/visual two-way communication—when available – is preferred, there are instances when this is not possible. This lack of access to technology, often impacting patients vulnerable to other disparities in care, will not

[5] https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020_Home-Infusion-Position-Statement.pdf
[6] https://ascopubs.org/doi/pdf/10.1200/jco.2008.21.1680
[7] https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020-ASCO-Interim-Position-Statement-Telemedicine-FINAL.pdf
[8] https://www.asco.org/sites/new-www.asco.org/files/content-files/practice-and-guidelines/documents/2020-PracticeNET-COVID19-Insights.pdf
[9] https://ascopubs.org/doi/pdf/10.1200/jco.2008.21.1680

be limited to the time during the PHE; therefore, we urge the agency to permanently cover and reimburse audio-only services beyond the PHE.[10]

115 – Use of Telecommunications Technology Under the Medicare Home Health Benefit

ASCO supports CMS' proposal to permit patient services and/or monitoring performed through telecommunication technology on a permanent basis when such services are included as part of the home health plan of care.

ASCO supports CMS' proposal to make this temporary flexibility provided during the COVID-19 PHE a permanent part of the Medicare home health program. This proposal will ensure patient access to the latest technology and give home health agencies the confidence that that they can continue to use telecommunications technology as part of patient care beyond the PHE. Cancer patients, because they are often immuno-compromised, are an especially vulnerable subset of the Medicare population. Granting HHAs the flexibility to provide clinically appropriate and high-quality care to these beneficiaries through technology can help keep these vulnerable patients in their homes, reducing unnecessary exposure to all illnesses, not just COVID-19.[11]

122 – Physician Supervision Flexibility for Outpatient Hospitals—Outpatient Hospital Therapeutic Services Assigned to the Non-surgical Extended Duration Therapeutic Services (NSEDTS) Level of Supervision

We believe this flexibility to change the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and critical access hospitals (CAHs) may have many positive effects on physician workload. Permanent implementation could allow physicians to devote more time to clinical work and allow more flexibility on the part of cancer clinics to provide more timely care.

ASCO remains committed to ensuring that cancer patients have access to high quality and safe care. While we support CMS's proposal, we urge CMS to carefully monitor its implementation to ensure that it does not unintentionally place some patients at elevated risk for medical errors.

125 – Payment for Medicare Telehealth Services Under Section 1834(m) of the Act; and
149 – Updating the Medicare Telehealth List on a Sub-regulatory Basis

ASCO supports the permanent coverage and inclusion of additional services on the Medicare telehealth list, and we encourage CMS to continue soliciting stakeholder comments and feedback regarding potential future additions.

In our interim position statement,[12] ASCO urges CMS to extend the expanded telemedicine policies after the expiration of the PHE. We support the permanent and temporary addition of services to the telehealth list, as this has the potential to increase access to services for cancer patients.

[10] https://www.asco.org/sites/new-www.asco.org/files/content-files/ASCO-MPFS-QPP-2021-Comments.pdf
[11] https://www.asco.org/sites/new-www.asco.org/files/content-files/2020-2021-Home-Health-Comment-Letter.pdf
[12] https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020-ASCO-Interim-Position-Statement-Telemedicine-FINAL.pdf

Additionally, ASCO urges CMS to evaluate the safety, quality of care, and outcomes resulting from telehealth visits and to consider such evidence and specialty input when considering additions in future rulemaking.[13] Since CMS has the authority to add services to the list of covered Medicare telehealth services, we support updates to the Medicare Telehealth list on a sub-regulatory basis where there is demonstrated clinical benefit to the patient and other requirements are met.

B. Testing/PPE - ASCO supports long-term and widespread distribution of any COVID-19 testing, treatment, or vaccine, to ensure accessibility to health care providers and disadvantaged populations. ASCO urges the Agency to consider prioritizing resources in a transparent and ethical way.

74 – Policy for Coronavirus Disease 2019 Tests During the Public Health Emergency (Revised)

ASCO believes there is a need for FDA premarket regulatory review for high risk tests in addition to CMS CLIA oversight. Physicians rely on high quality and accurate tests to appropriately diagnose and treat patients. There is also a need for flexibility in the review and approval of these tests particularly to inform cancer treatment planning. This flexibility is particularly important in oncology, as new information develops rapidly and is disseminated widely, leading to demand by both physicians and patients for new tests that impact medical decision-making.

C. Access - As the leading organization for physicians and oncology professionals caring for people with cancer, ASCO is committed to promoting access to high quality, high value cancer care.

29 – Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act Guidance for Industry;

30 – Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act During the COVID–19 Public Health Emergency; and

61 – Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID– 19 Public Health Emergency

ASCO supports the continuation of policies to enhance transparency in the drug supply chain, assess and strengthen the Food and Drug Administration's (FDA) efforts to prevent shortages, and empower the FDA to have drug makers identify and address vulnerabilities in the supply chains to ensure access to critical medications.

The spread of novel viruses such as COVID-19, and natural disasters such as hurricanes, have highlighted vulnerabilities in the drug supply chain that can lead to significant shortages of critical medications throughout the world. United States drug manufacturers currently rely on China for a majority of their active pharmaceutical ingredients, and this issue is being highlighted by the current COVID-19 epidemic. A disruption in the supply chain, whether caused by manufacturing or quality issues, will likely leave many patients without the critical medications they need.

[13] https://www.asco.org/sites/new-www.asco.org/files/content-files/ASCO-MPFS-QPP-2021-Comments.pdf

ASCO urges CMS to make permanent policies that would ensure information about shortages is publicly available. Providing the FDA with the necessary authority to ensure that drug makers increase transparency in their supply chains and identify and address potential manufacturing and quality issues, is critical to guaranteeing patient access to needed medications.

221 – Part D ''Refill-Too-Soon'' Edits and Maximum Day Supply

226 – Prior Authorization;

227 – Home or Mail Delivery of Part D Drugs;

285 – Prior Authorization [Medicare Advantage]; and

288 – Prior Authorization for Part D Drugs.

ASCO urges HHS to implement long-term policies to eliminate longstanding barriers to access associated with utilization management policies within the Medicare program, including Medicare Advantage and Medicare Part D, as well as Medicaid.

ASCO has always advocated for adherence to high quality clinical pathways as a mechanism to drive appropriate use of medications, rather than arbitrary utilization management policies that largely focus on cost rather than clinical evidence. Temporary policies during the pandemic have relaxed certain utilization management strategies during the pandemic. ASCO appreciates the relaxation of policies like "refill-too-soon" edits, giving patients the ability to obtain the maximum extended day supply available under their plan to allow an uninterrupted supply of critical medications. This is critical support at a time when disruptions to routine care may be expected.[14] However, despite the attempt to relax utilization policies, ASCO members report they still experienced significant delays in care resulting from prior authorization requirements, particularly related to imaging. The pandemic has highlighted the need for permanent solutions to utilization barriers. ASCO continues to work with the AMA and others to achieve reforms related to utilization management. We call on the Agency to put renewed emphasis on addressing this longstanding and increasing burden on patients and their providers.

Restrictive networks and requirements for patients to use designated specialty pharmacies for Part D drugs can impair patient care and access. Patients with cancer should be allowed to seek the services of their preferred pharmacy, including dispensing physicians. For cancer patients, this is important as some studies have suggested that practices with medically integrated services may improve patient adherence to treatment regimens.

D. Quality Payment Program– ASCO encourages the Agency to continue flexibilities in quality reporting across all programs for two years, allowing these flexibilities to remain in effect through performance year 2022. This offers critical time for physician practices to adjust and begin to recover from the repercussions of the COVID-19 pandemic.

106– Merit-based Incentive Payment System (MIPS) Updates

[14] https://www.asco.org/sites/new-www.asco.org/files/content-files/2020-COVID19-IFC1-Comment-Letter.pdf

ASCO supports the flexibilities provided to MIPS eligible clinicians to receive hardship exemptions for performance years 2020 and 2021. We encourage the Agency to enable these flexibilities through performance year 2022 to allow practices to recover from the impact of the PHE.
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 support flexibilities provided to MIPS eligible clinicians and group practices to choose to submit data or to apply for—and in some circumstances, receive automatically—a hardship exemption. Allowing these flexibilities to remain in effect through performance year 2022 will be important to recovery from the repercussions of COVID-19 and to preserving access to care in communities across the US. [15]

ASCO supports 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.

ASCO supports CMS' designation of data entry to clinical registries as a qualified Improvement Activity for clinicians who are caring for COVID-positive patients. 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. 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 submit meaningful improvement activity data that reflect real-world events and that are of value to patients and clinicians.[16]

With the following recommendations, we aim to make cancer research opportunities more accessible and equitable for patients in every community.

Part II: Clinical cancer research – Implementation of policies to ensure the clinical trials system is more resilient and flexible, and more accessible to patients must be a priority. Specifically:

Increase patient access and equity – by continuing remote and virtual approaches to consent, and other trial procedures; and by better integrating trials into routine cancer care

[15] https://www.asco.org/sites/new-www.asco.org/files/content-files/2020-COVID19-IFC1-Comment-Letter.pdf
[16] https://www.asco.org/sites/new-www.asco.org/files/content-files/ASCO-COVID-19-IFC3-Comment-Letter.pdf

Increase trial efficiency – by streamlining and standardizing regulatory and training requirements; and using central Institutional Review Boards and innovative trial designs, including adaptive trials, master protocols, and common control groups

Increase flexibility so research will be more resilient in future crises – for example, by "cross training" research teams so that key functions can be led by various team members; and by sustaining flexibility, adopted during the pandemic, for site selection, initiation, and data collection.

ASCO also encourages the Agency to support enhanced data collection efforts to understand the impact of COVID-19 on patients with cancer, including its effect on social determinants of health.

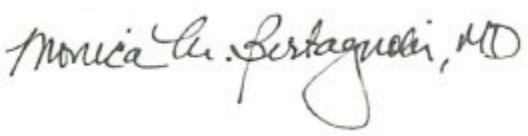
Additional recommendations related to Cancer Care Delivery can be found in the Road to Recovery Report.

ASCO recommends the following policy be permanently implemented after the PHE.

> 33 – Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID–19 Public Health Emergency
>
> ASCO continues to support the use of central IRBs as one way to promote efficiency, oversight, and review of clinical trial conduct, reduce costs and eliminate duplicative reviews by multiple institutions. During COVID-19, central IRBs were important in expediting research on testing and treatment. ASCO supports expanded access to address unmet needs for many patients and the approval to access investigational therapies should continue to be done so with establish standards of safety and efficacy.

Many of the flexibilities implemented during the PHE have indeed provided relief in managing the unprecedented crisis presented by the COVID-19 pandemic. We encourage the agency to make determinations regarding the future implication of policies and practices based emerging data, and lessons learned, and the experiences of patients, physicians, care teams and health systems, researchers, and research programs during the COVID-19 pandemic. We thank you for the opportunity to provide feedback. Should you have any questions, please contact Gina Baxter at gina.baxter@asco.org or Karen Hagerty at karen.hagerty@asco.org.

Sincerely,



Monica M. Bertagnolli, MD, FACS, FASCO

Chair of the Board

ASCO Association for Clinical Oncology