August 12, 2019

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

Subject: Request for Information; Reducing Administrative Burden to Put Patients Over Paperwork; RIN 0938-ZB54

Dear Administrator Verma:

The American Society of Clinical Oncology (ASCO) appreciates your Request for Information (RFI) on Patients over Paperwork (published in the Federal Register June 11, 2019), seeking stakeholder input on ways to reduce the regulatory and administrative burden patients and physicians face which pose barriers to effective and efficient patient care. We are pleased to share our ideas for improving the delivery of cancer care in a way that is beneficial for patients and oncology professionals.

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

The Centers for Medicare and Medicaid Services play a key role in advancing health care policies that lead to high-quality, high-value care for millions of patients receiving care through the Medicare and Medicaid program as well as those enrolled in exchange plans under the Affordable Care Act. It is important that the Agency take the necessary steps to alleviate regulations and mandates which impede innovation, increase costs, and prevent the delivery of better care to enrollees in those programs. Generally, ASCO offers suggestions for regulatory improvement in the following areas:

- Utilization Management: Prior Authorization
- Aligning Medicare, Medicaid and Other Payer Coding/Billing, Payment and Documentation Requirements and Processes
- Adoption of High-Quality Clinical Pathways
- Refinements to the Quality Payment Program and Oncology Care Model

Thank you for the opportunity to participate in this important initiative.

Sincerely,

[ASCO Letterhead]
• Adoption of the Patient-Centered Oncology Payment Model (PCOP)
• Exclusion of Medicare Drug Cost from Resource Use in Cancer Care
• Improvement of Access to Claims Data
• Protection for Practices and Patients in Rural Settings
• Quality Measure Alignment
• Promotion of Interoperability

Additional detail on the issues posed by certain regulatory requirements are laid out below.

Utilization Management: Prior Authorization

Increasingly, policymakers and payers are seeking more robust approaches to achieving high value care. We agree that tools like prior authorization can play a role in managing cost, but such strategies must be used appropriately to avoid restricted and/or delayed access to care and potentially harmful outcomes. CMS can play an important role in protecting patients from harmful policies which impede their care.

ASCO members are subject to unnecessary administrative burdens imposed by existing utilization management policies. An ASCO survey published in the 2017 State of Cancer Care in America report found that 78% of oncology practices cited prior authorization as a significant “payer pressure.” In a separate survey conducted by the American Medical Association (AMA), medical practices indicated that on average they conducted 37 prior authorization requests per physician weekly, taking an average of 16 hours of clinician time. CMS could ease these burdens by implementing recommendations in the Medicare and Medicaid program that ASCO has made in earlier comment letters to CMS and in our policy statement, including standardized processes and forms and integrating prior authorization processes into EMRs. ASCO will also be submitting comments to the agency on electronic prior authorizations, and we believe that this is a positive step towards resolving many of the issues for the Medicare Part D Program. Our recommendations, however, would be relevant to all of Medicare and to Medicaid.

Beyond the administrative burdens, these utilization management policies are impacting patient care. In our 2016 “Statement on the Impact of Utilization Management Policies for Cancer Drug Therapies” ASCO outlined instances where prior authorization policies had adverse consequences on individuals with cancer, including suboptimal clinical outcomes, increases in adverse events, and increases in emergency department visits. In the statement, ASCO offered the following guidelines to 1) facilitate appropriate implementation of prior authorization policies and 2) eliminate many of the barriers patients and physicians frequently experience.

• Develop and use standardized prior authorization request forms and processes to alleviate the administrative burdens placed on treating oncology teams or practices
• Use a public process to determine prior authorization policies for cancer treatment, reflecting the most up-to-date standards of care and including consultation with oncologists
• Restrict prior authorization policies to drugs where specific concerns about inappropriate use and/or undesirable variation exist
• Ensure oncologists make prior authorization determinations in cancer care and provide treating oncologists with direct access to that oncologist to discuss the clinical circumstances as necessary
• Integrate prior authorization processes into electronic health records to support authorization at the points of care, minimizing delays in treatment and administrative burden on providers
• Establish efficient and responsive appeals processes, including 48-hour completion of review/decision on appeals for oncology and expedited review for patients whose clinical circumstances require urgent treatment
• Do not use appeals mechanisms to compensate for underlying deficiencies in prior authorization policies or processes
• Monitor and remedy the predictable, adverse consequences that individuals with cancer may experience from barriers or delays in receiving preferred oncology therapies as a result of prior authorization requirements, including suboptimal clinical outcomes, increases in adverse events, and increases in emergency department visits
• Ensure continuity for patients receiving a course of therapy upon enrollment in a health plan to prevent mandatory substitution or interruptions in treatment

Aligning Medicare, Medicaid and Other Payer Coding/Billing, Payment and Documentation Requirements and Processes

For physicians, whose primary goal is to provide optimal care to patients, the variation in requirements across multiple payers is both burdensome and a barrier to effective delivery of care. CMS, like many other payers, is undertaking major initiatives to transform care delivery to facilitate access to high value care. The requirements for these programs, with respect to coding and billing, documentation, reimbursement, and care management are as varied as the number of programs available. By aligning the requirements, CMS would eliminate a major source of administrative burden for participating providers.

For example, ASCO members have reported that each Medicare Advantage plan has different forms, requirements, and timelines for prior authorization. This means office staff, including physicians, must learn a new set of protocols and abide by varying timelines for each plan. The administrative burden associated with prior authorization alone substantially decreases the amount of time physicians are able to spend face-to-face with patients, affecting the providers’ ability to provide the standard of care necessary to produce improved health outcomes.

In its proposed rule for the 2020 physician fee schedule, CMS has proposed finalizing five levels of new patient visits, four levels of established patient visits, and changes to requirements in documentation and verification in the patient electronic medical record. While we applaud CMS for seriously considering stakeholder feedback and making changes of importance to the provider community, we remain concerned that varying requirements across payment plans will result in parallel and duplicative documentation requirements. We urge CMS to extend its focus on streamlining administrative burden by working with the physician community to standardize documentation and other administrative requirements for compliance and utilization management across all Medicare contractors.

Encourage Adoption of High-Quality Clinical Pathways

ASCO strongly supports the utilization of high-quality value-based oncology clinical pathways. As health care payment models continue to advance, private insurers have already embraced the use of oncology clinical pathways that incorporate both evolving scientific evidence and considerations of cost and value.
We have encouraged the Medicare program to adopt high-quality value-based pathways as a mechanism to assure the highest quality and most appropriate care for Medicare patients facing a cancer diagnosis.

Clinical pathways are regularly updated treatment protocols that map care based on current scientific evidence. When used appropriately, high-quality pathways can reduce unwarranted variations in care and focus resources on the most appropriate and valuable therapies, while still allowing for justifiable individualized decision-making. Placing adherence to clinical pathways at the center of an oncology-based care model can improve both quality and efficiency of medical oncology services for Medicare beneficiaries, and would align Medicare policy with ongoing pathway initiatives in use by commercial payers.

ASCO has done extensive work examining pathways in oncology and has developed robust criteria for the development and implementation of pathway programs. ASCO has used these criteria to assess several of the major clinical pathway vendors in the U.S. For more information on clinical pathways please visit: https://www.asco.org/practice-guidelines/cancer-care-initiatives/clinical-pathways.

Refinements to the Quality Payment Program and Oncology Care Model

Since enactment of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), ASCO has provided support to its members through education and training to ensure practice success and delivery of high quality, high value care to cancer patients. As the Quality Payment Program goes into its fourth year of operation in 2020, we believe that there are important improvements that would help practices to thrive, while meeting the original intent of the MACRA law.

In addition to participating in the Merit-based Incentive Payment System (MIPS), and Alternative Payment Models (APMs) with private payers, ASCO members also participate in the Center for Medicare and Medicaid Innovation (CMMI) sponsored Oncology Care Model (OCM) and other CMMI sponsored models. As a strong advocate of high-quality, high-value care, ASCO has supported development of new payment models that include the full scope of services needed by patients facing a cancer diagnosis.

A key component of the OCM is the sharing of Medicare claims data, which provides physicians the information necessary to understand total cost of care borne by Medicare and its beneficiaries. Analysis of these data has highlighted opportunities to reduce health care costs. We have heard from participating practices that oncology-specific care management payments, such as OCM’s monthly-enhanced oncology service (MEOS) payments, provide funding to support resources such as navigators, triage nurses, and palliative care specialists. This helps to mitigate some of the costs for these previously uncovered services that are critical to quality care in oncology. However, we note that, for many practices, a large portion of the MEOS payment has been consumed by administrative support needed to comply with required reporting and analysis of data. This has drawn MEOS payments away from the intended patient support services and is, therefore, an area where ongoing discussion will be important.

Practices participating in APMs continue to undergo transformation. Many have reported hiring clinical and financial navigators to improve coordination of care and proactively manage symptoms that would
otherwise lead to acute care admissions or other long-term expenses. Practices have also employed value-based decision support tools, such as treatment and triage pathways.

Overall, participation in these payment models has resulted in fewer hospital admissions, improved performance on end-of-life quality measures, and increased patient satisfaction. However, the number of alternative payment models available to oncologists is still limited. We encourage continued investment in innovation, including creation of a multi-step process for practices to transform and engage in advanced alternative payment models. Through small-scale testing of multiple oncology-focused APMs, CMS can highlight potentially successful strategies for the broader community of cancer patients and oncology professionals.

Oncology practices exist in numerous forms, and a “one size fits all” approach to payment models fails to take advantage of the strength of each of these practice structures. In this context, care should be taken not to disadvantage small and rural practices, which play a crucial role in oncology care.

**Adopt the Patient-Centered Oncology Payment Model (PCOP)**

Medicare coding and payment for outpatient cancer treatment could be transformed by adopting proposals such as ASCO’s “Patient-Centered Oncology Payment Model” (PCOP) and by implementing policies that are consistent with that model. Originally published in 2015, ASCO has recently convened a diverse team of clinicians, payer and employer representatives to update the PCOP model and incorporate learnings from OCM and multiple commercial payer models.

The updated PCOP incorporates a community-centric oncology medical home structure that encourages a true multi-payer approach. The use of evidence-based clinical treatment pathways is a cornerstone of the PCOP model, along with measurement and rewards for high-quality, high-value care.

A draft of the updated PCOP model has already been provided to the CMMI and will be submitted to the Physician-Focused Payment Model Technical Advisory Committee later this year. We encourage CMS to adopt the PCOP as an additional APM for oncology providers.

**Exclude Medicare Drug Cost from Resource Use in Cancer Care**

ASCO has urged CMS to exclude all Medicare Part B and D drug costs from the assessment of cost performance and refrain from increasing the weight of cost performance category in the MIPS scoring methodology until it implements a cost measurement methodology that fairly and accurately assesses resource use in cancer care.

Because of unique characteristics of cancer care, the current cost measurement methodologies are inadequate for measuring cost performance by oncology-focused providers and practices. Treatment decisions are highly dependent upon a patient’s unique medical characteristics, including their cancer morphology, cancer stage, genetic characteristics, mutation status, comorbidities and patient preferences. Individual physicians often specialize in treating specific types of cancer that may be especially complex or expensive to treat. Protecting the most vulnerable Medicare beneficiaries will
require CMS to account for these considerations without threatening the viability of subspecialties that focus on treating certain cancers.

**Improve Access to Claims Data**

CMS should enhance access to its claims data, as intended by Congress in the MACRA legislation. MACRA required CMS to make its data easier to access, especially for the purpose of linking clinical registries to CMS claims data. To date, CMS has conditioned access to these data on use of its existing ResDAC process, which is cumbersome, time consuming to navigate, and strictly limits use of the data. We were pleased to note CMS’ announcement this month of its “Data at the Point of Care” (DPC) pilot project, which would provide select physicians access to structured and complete claims data available directly within their workflow. We urge CMS to move forward with this pilot and to expand it as expeditiously as possible, while prioritizing patient safety and privacy.

**Protect Practices and Patients in Rural Settings**

While CMS has taken concrete steps to assist small practices participating in MIPS, such as freely available technical assistance and special considerations related to their scoring in the MIPS framework, small and rural practices fared less well than their urban counterparts under MIPS in the first performance year (2017): the overall national mean score for a clinician was 74 points, but clinicians in small and rural practices had national means of 43 points and 63 points, respectively. CMMI should work with specialty societies to explore ways that small and rural practices can participate—and enhance—innovation in cancer care delivery. It is likely that some strategies to enhance rural health care could also improve health care delivery more broadly. ASCO recently established a task force on rural health and we would welcome the opportunity to explore potential collaboration with CMS in this area.

**Quality Measure Alignment**

When measuring quality, it is important to choose a set of measures that accurately reflects practice realities and is meaningful regarding patient outcomes. CMS should ensure that quality measures relating to cancer care focus on the specifics of cancer treatment, are meaningful to patients and relevant in all oncology disciplines or specialties. Alignment of measures across all payors, including Medicaid managed care plans and the Medicare program, would reduce the burden associated with quality reporting and facilitate delivery of high-quality, high-value care.

Current quality measures and payment programs rely too heavily on documenting irrelevant tasks, representing an administrative burden on physicians, and reducing time focused on the patient. For more than a decade, ASCO has offered to its members the Quality Oncology Practice Initiative (QOPI®), a comprehensive quality program that includes robust, oncologist-developed quality measures, which allows providers to report clinically relevant quality measures for cancer care that promote value and protect patients during cancer treatment. Separately, ASCO maintains both a QCDR and qualified registry that are currently accepted by CMS for use in the Quality Payment Program.

Creation of new measures that are meaningful and reflective of modern oncology practice requires standard documentation of essential data elements. For example, the documentation of treatment
intent, performance status and communication of treatment plan/summary are building blocks for the development of meaningful measures focused on the patient experience. However, current limitations of such cancer measures in federal programs have hindered the ability of oncologists to report on these important aspects of cancer treatment. Finally, practice medical staff spend an excessive amount of time completing required Electronic Health Record (EHR) documentation, which draws significant time away from direct patient care. ASCO urges CMS to significantly scale back data reporting requirements and engage with specialty societies to establish measures meaningful to the patients they treat. In addition, ASCO urges CMS to aggressively pursue interoperability of EMRs to reduce administrative burden.

**Promoting Interoperability**

Interoperability and the free exchange of health care information are core components to realizing the potential of a value-based health care system. ASCO commends CMS for reforming the Promoting Interoperability (PI) performance category measures to emphasize the exchange of health information, but we remain concerned that the scoring for this category remains essentially “all or nothing,” which places a heavy penalty on practices that fail to meet one of the criteria. We understand that CMS is exploring potential options to move toward more customized scoring of this category through incentives for innovative use of HIT and the agency seems to have built on that concept of flexibility in its proposal for new “MIPS Value Pathways” (MVPs) contained in the recent proposed rule on the physician fee schedule and the Quality Payment Program (released July 29, 2019). ASCO is eager to discuss ideas for how this could be accomplished with CMS.

Despite our many steps forward in this area, oncology practitioners are still plagued by a lack of interoperability between different types of electronic medical records (EMRs)—and a lack of interoperability between EMRs and other forms of health information technology, including electronic systems such as registries, genomic testing laboratories, and hospital laboratory information systems. These types of technology hold great promise for improving and enhancing patient care, especially in the realm of care coordination and quality improvement. To further enhance healthcare quality, we should move with urgency towards realizing the vision of seamlessly integrated health information, easily and securely accessible to all patients.

A foundational need to achieve this goal in the field of oncology is creation of a common, shared set of data elements used to exchange information between providers and patients. ASCO, supported by MITRE, the Alliance for Clinical Trials in Oncology Foundation, and the Oncology Center of Excellence of the U.S. Food and Drug Administration, in 2018 convened a multidisciplinary group of subject matter experts, including oncology clinicians, informaticists, health services researches, experts in data standards and interoperability, and others to develop a set of “Minimal Common Oncology Data Elements” (mCODE™). This effort produced a parsimonious set of consensus-developed oncology data elements necessary for critical information exchange between EHRs, for clinical care, quality reporting, and other use cases. This set of oncology data elements, which was publicly released June 1, 2019 and is available free of charge at www.mCODEinitiative.org, is envisioned by ASCO to form the basis of an initial, essential set of data that should populate all electronic health records (EHRs) serving patients with cancer. We are currently engaged in pilot projects at two large healthcare systems in the U.S. as proof of concept, in anticipation of wider adoption of these oncology data elements, which we believe would streamline communication between care providers and positively impact patient care.
We note that the close of the comment period for this RFI comes just days after the release of the annual proposed rule outlining changes to the Medicare Physician Fee Schedule, the Quality Payment Program, and other provisions in the Medicare program. While it possible for the Agency to collect public comment and still release the final rule in time to meet the 60-day advance notice for the beginning of the 2020 calendar year, we are concerned that consideration of that public feedback will be compressed. We encourage the Agency to make every effort to fully consider all comments --some of which will be important to other issues raised in this letter--before publishing the final rule. If, in fact, this causes a delay in the release of the final rule, we urge the Agency to consider delaying the implementation of some of the provisions of the rule.

ASCO looks forward to working with CMS to accomplish these important goals for patients with cancer to ensure each receives positive health outcomes. For question about this or other issues related to Patients over Paperwork, please contact Karen Hagerty (karen.hagerty@asco.org).

Sincerely,

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President, American Society of Clinical Oncology