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U.S. House Committee on Energy and Commerce Subcommittee on Health

What's the Prognosis?: Examining Medicare Proposals to Improve Patient Access to Care & Minimize Red Tape for Doctors

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The Association for Clinical Oncology (ASCO) is pleased to submit this statement for the record of the hearing entitled, "What's the Prognosis?: Examining Medicare Proposals to Improve Patient Access to Care & Minimize Red Tape for Doctors." ASCO appreciates the Subcommittee holding today's hearing to discuss policy reforms to create a more sustainable Medicare physician reimbursement system.

ASCO is a national organization representing nearly 50,000 physicians and other health care professionals who care for people with cancer. ASCO members are dedicated to conducting research that leads to improved patient outcomes and are also committed to ensuring that evidence-based practices for the prevention, diagnosis and treatment of cancer are available to all Americans, including Medicare beneficiaries.

ASCO supported the passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) as a replacement for the flawed Sustainable Growth Rate (SGR) formula for Medicare physician reimbursement. Since its enactment, ASCO has provided extensive education to its members as well as significant input to the Centers for Medicare and Medicaid Services (CMS) around necessary refinements to the program to ensure its efficacy in the agency and for Medicare beneficiaries they serve. Unfortunately, physicians still face the same uncertainty MACRA was intended to address – financial instability within the Medicare payment system.

We are encouraged by the Subcommittee's interest in addressing current challenges and look forward to collaborating on ways to ensure long-term stability in the Medicare payment system. ASCO offers to be an ongoing resource for you as you evaluate the financial sustainability of the Medicare physician payment system, MACRA's effectiveness and the continued transition to a value-based payment system.

ASCO's History of Quality Improvement

Since its founding over 50 years ago, our affiliate organization, the American Society of Clinical Oncology (the Society), has been dedicated to the delivery of high-quality, high-value care for every patient with cancer - every day, everywhere. The Society has a wide range of resources and programs aimed at improving the standard of cancer care received by patients in the United States and around the world.

Oncology care is entering a time of unprecedented progress in both the understanding and treatment of cancer. However, today's medical practice environment is facing significant disruption, which threatens oncologists' ability to deliver the high-quality cancer care that patients deserve. Ongoing consolidation of physician practices, escalating cost of care, workforce shortages and physician burnout are on the rise and administrative burden has never been greater.[1,2,3,4,5] As cancer care professionals navigate these challenges, they are looking for models that enable the delivery of high-quality, high-value cancer care and a framework that supports success regardless of payment arrangements and other administrative policies.

In response to this need, in July 2021, the Society launched its ASCO Patient-Centered Cancer Care Certification initiative. This program promotes the oncology medical home as an effective approach to assuring every patient with cancer achieves the best possible outcome for their disease. It offers oncology group practices and health systems a single set of comprehensive, expert-backed standards for patient-centered care delivery.

The now permanent program (ASCO Certified) is based on Oncology Medical Home (OMH) standards from the American Society of Clinical Oncology and the Community Oncology Alliance (COA). These standards establish core elements needed to deliver equitable, high-quality cancer care and offer all stakeholders clarity on elements they should expect to see from cancer care teams. The OMH standards focus on seven different domains of cancer care, including patient engagement; availability and access to care; evidence-based medicine; equitable and comprehensive team-based care; quality improvement; goals of care, palliative and end-of-life care discussions; and chemotherapy safety.

The pilot included ninety-five cancer care sites and nearly five hundred oncologists from twelve participating practice groups and health systems in a variety of settings, including community, hospital, and academic settings. Two commercial insurers participated, and others expressed strong interest. Participating practices use the ASCO Quality Reporting Registry (AQRR) for ongoing measurement of quality, outcomes, and utilization measures. Performance data are derived from electronic health records, insurance claims, patient satisfaction surveys, and clinical pathways systems.

Practices meeting the rigorous ASCO-COA Oncology Medical Home Standards are certified by the ASCO Certification Program. Certified practices are expected to sustain adherence to the ASCO-COA OMH standards demonstrated through ongoing assessment and improvement activities monitored and evaluated by the ASCO Certification Program.

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[1] https://www.ama-assn.org/system/files/prior-authorization-survey.pdf
[2] https://ascopubs.org/doi/full/10.1200/OP.21.00644
[3] https://www.astro.org/ASTRO/media/ASTRO/News%20and%20Publications/PDFs/ASTROPriorAuthorizationPhysician- SurveyBrief.pdf
[4] https://old-prod.asco.org/sites/new-www.asco.org/files/ASCO-Prior-Auth-Survey-Summary-November-2022.pdf
[5] https://www.mgma.com/getmedia/788a1890-8773-4642-9c22-b224923e4948/05-03-2023_PA-in-MA_FINAL.pdf.aspx?ext=.pdf

Additionally, ASCO's Quality Oncology Practice Initiative (QOPI®) Certification Program provides a three-year certification recognizing high-quality care for outpatient hematology-oncology practices within the United States and certain other countries. Its primary focus is the safe delivery of chemotherapy in the outpatient setting. Practices receive QOPI Certification based on their full compliance with QOPI Certification Standards as assessed during an on-site survey.

Enhancing Oncology Model

In June 2022, the Center for Medicare and Medicaid Innovation (CMMI) announced a new, 5-year voluntary oncology payment model, the Enhancing Oncology Model (EOM), which began on July 1, 2023. Participating oncology practices are taking on financial and performance accountability for episodes of care surrounding systemic chemotherapy administration to patients with seven common cancer types: breast cancer, chronic leukemia, small intestine/colorectal cancer, lung cancer, lymphoma, multiple myeloma, and prostate cancer. EOM participants are responsible for the total cost of care during a six-month episode and elect to participate in one of two, two-sided financial risk arrangements.

EOM employs specific design elements, including comprehensive, coordinated cancer care; data-driven continuous improvement; payment incentives, including a Monthly Enhanced Oncology Services (MEOS) payment and a performance-based payment (PBP) or a performance-based recoupment (PBR); an aligned multi-payer structure; and focused efforts to identify and address health disparities.

EOM participants are required to implement participant redesign activities, including 24/7 access to care, patient navigation, care planning, use of evidence-based guidelines, use of electronic Patient Reported Outcomes (ePROs), screening for health-related social needs, use of data for quality improvement, and use of certified electronic health record technology. As part of the data reporting for quality improvement, EOM participants will submit health equity plans to CMS, where participants detail evidence-based strategies to mitigate health disparities identified within their beneficiary populations.

ASCO is pleased that EOM is a voluntary model and that practices were able to choose to participate based on their level of readiness and ability to assume financial risk. We fully support CMMI's focus on equity and coordinated cancer care. The cancer care delivery requirements of the CMMI EOM have many similarities with ASCO-COA Oncology Medical Home Standards and ASCO Certified. Practices achieving ASCO Patient Centered Cancer Care Certification will be well positioned to succeed in the EOM.

We are concerned, however, that CMMI significantly reduced MEOS payments compared to similar payments in the earlier Oncology Care Model (OCM). This is especially concerning given that there was a one-year gap between the end of OCM and the start of EOM, during which time practices received no additional support for the mechanisms instituted during OCM to enhance patient access and care coordination that are continuing under EOM. The limited MEOS may not cover the practice redesign efforts needed in this model with financial risk.

While OCM prompted practice changes that enhanced patient-centered care, those changes cannot be sustained or broadened to other practices without a regulatory and payment framework that supports them. We are eager to work with CMS and Congress to enable the practice transformation critical to practices surviving and thriving in the years ahead, so patients receive the care they need and deserve.

Below are areas of improvement we believe are vital to achieving high-value, high-quality care for all patients with cancer.

Medicare Physician Payment Reform

In repealing the SGR, MACRA specified a 0% update to the Medicare Physician Fee Schedule (MPFS) Conversion Factor (CF) for a period of six years, followed by a 0.25% annual increase for Merit Based Incentive Payments System (MIPS) participants and a 0.75% annual increase for Advanced Alternative Payment Model (APM) participants thereafter. While Congress provided temporary relief in 2021 and 2022, physician reimbursement was cut in 2023. In the Consolidated Appropriations Act of 2023, Congress reduced the proposed 4.5% cut to Medicare physician payments by increasing the 2023 conversion factor by 2.5%.

Failure of the MPFS to keep up with increasing labor, supplies, rent, and other practice expenses influences a growing site-of-service shift from independent physician practices to off-campus outpatient hospital departments paid for by the Outpatient Prospective Payment System (OPPS). Rather than addressing the lack of sufficient payment under the MPFS, Congress directed CMS to reduce payments to new off-campus outpatient hospital departments, thereby encouraging further shifts into on-campus departments. Instead of encouraging value-based care, this consolidation results in reduced beneficiary access to community-based healthcare services. Congress must ensure that future payment updates within the MPFS are sufficient to sustain beneficiary access to community-based physician care.

While we appreciate Congress' efforts to help stabilize physician payment, ASCO hopes to see a longer-term solution. We strongly support and encourage lawmakers to support the *Strengthening Medicare for Patients and Providers Act* (H.R. 2474). This legislation aims to provide an annual update to a single conversion factor under the MPFS that is based on the Medicare Economic Index (MEI). This inflationary increase will help providers keep up with rising healthcare costs. Moreover, ASCO appreciates and supports the Subcommittee's consideration of the *Providing Relief and Stability for Medicare Patients Act of 2023* (H.R. 3674) and the *Provider Reimbursement Stability Act of 2023*, legislation that would increase resources across all Medicare service codes. Following the initial increase, the fee schedule would see annual adjustments based on the MEI. ASCO appreciates the inclusion of the provision to update direct costs associated with practice expense relative value units (RVUs) once every five years. Lastly, both bills would address over- and under-utilization estimates, which impacts budget neutrality in the MFPS. These consistent investments in Medicare services are crucial to the vitality of our profession and the quality of care we provide.

MIPS Budget Neutrality and the Exceptional Performance Bonus

For payment year 2021, there were a total of 954,664 MIPS-eligible clinicians under the Quality Payment Program (QPP) MIPS track.[6] Of that total number, 951,744 (99.7%) avoided a negative payment adjustment. Almost 84% achieved exceptional performance and earned positive payment adjustments ranging from +0.09% to +1.79%. Only those clinicians scoring high enough to earn an exceptional performance bonus actually received any positive payment adjustment. Clinicians who received a

[6] 2021 Quality Payment Program Experience Report. Available at: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2433/2021%20QPP%20Experience%20Report.pdf

positive score, but did not reach the exceptional threshold, received a payment adjustment of 0% due to the budget neutrality requirement of MIPS as established by MACRA (i.e., absent the "exceptional performance" bonus, the number of negative adjustments equals the number of positive adjustments). As only 0.31% of clinicians received a score below the threshold (and received a 7% penalty), the only real source for a positive payment adjustment came from the $500 million annual "exceptional performance" bonus. With the sunsetting of the ability to earn this bonus in performance year 2022, it is very likely that high-scoring clinicians participating in MIPS going forward will receive little to no positive adjustment through MIPS; this is compounded by the 0% statutory update to the MIPS track until 2026 and the lack of an inflationary update to the MPFS.

When the MIPS track of the QPP was originally envisioned, it was thought that a budget-neutral system would provide rewards to high performers, while penalizing low performers. Experience has shown us that small and rural practices disproportionately bear the burden of growing penalties, which in the aggregate are far too small to result in any meaningful distribution to higher performers. The budget-neutral nature of MIPS should be re-examined, as should the exceptional performance bonus. We urge the Subcommittee to consider legislation to not only address budget neutrality in the MPFS as outlined above but also in MIPS.

Provider Participation in APMs

MACRA provided for a time-limited, annual payment incentive to Qualifying APM Participants (QPs) equal to 5% of estimated aggregate payment amounts for covered professional services. The incentive payment was intended to encourage participation in advanced APMs and has been critical in assisting physicians to develop the infrastructure necessary for the transition to value-based payment models.

Unfortunately, the combination of a lack of specialty-specific advanced APMs, financial uncertainty throughout the COVID-19 pandemic, and delays in the rollout of certain APMs (e.g., Oncology Care First, now named Enhancing Oncology Model) has resulted in many physicians being unable to qualify for this incentive. The payment incentive for advanced APMs was extended under the Consolidated Appropriations Act of 2022 for one year through 2023, with a 3.5% incentive payment for services covered in the 2023 performance year. The legislation also extended the current freeze on participation thresholds for qualification for APM bonuses for an additional year. While we appreciate Congress' efforts to ensure providers can successfully participate in value-based payment models in the short-term, longer-term solutions are necessary to address the incentive gap we are nearing. Specifically, we encourage Congressional support for Rep. Dunn's legislation to *extend incentive payments for eligible APMs for 5 years*. Additionally, Congress should consider long-term solutions, beyond the 5-year cap outlined in the legislation to ensure financial stability in the program.

Further, to qualify for the APM incentive, physicians must meet either the Medicare Payment Threshold Option or Medicare Patient Threshold Option. These thresholds are meant to ensure that physicians meaningfully participate in alternative payment models. Many specialty physicians will find it difficult to qualify under the currently specified thresholds. For example, oncologists who participate in a Medicare Shared Savings Program (MSSP) Accountable Care Organization (ACO) naturally have lower payment and patient threshold scores due to receiving referrals from primary care physicians outside of the ACO. As a result, many ACOs are considering whether to remove specialists from their participating physician lists so that the remaining physicians may be deemed QPs.

Even within specialty-specific models, specialists may find that the limited scope of models- the EOM includes only seven cancer types- makes it difficult to meet the specified thresholds. Congress should extend the current 50% payment threshold and 35% patient threshold and should also direct CMS to remove barriers to participation in multiple APMs, such as allowing a single practice (identified by a Tax Identification Number) to participate in multiple ACOs.

Lastly, ASCO appreciates the inclusion of the *SURS Extension Act* (H.R. 5395) in today's hearing. This legislation would extend CMS' Quality Payment Program-Small Practice, Underserved, and Rural Support program. Often, providers and practices in underserved or rural communities struggle to participate in the QPP due to a lack of resources and therefore require additional technical support.

Regulatory Relief and Patient Access

In addition to the harmful effects of inflation, practices are confronted daily with a growing number of utilization management policies payers use in attempts to lower costs. ASCO understands concerns about increased health care spending and supports the delivery of high-value care. However, we are concerned these practices are harming patients. They take clinician time away from patient care, increase practice expense with additional administrative workload, often delay treatment, and may require patients to travel long distances for additional appointments. We are in strong support of efforts to lift this burden from patients with cancer and the clinicians who care for them.

Regulatory Relief

An ongoing source of frustration across the oncology care team is overly burdensome prior authorization requirements. ASCO recently published the results of a U.S. member survey to assess the impact of prior authorization on cancer care.

Nearly all survey participants reported a patient has experienced harm because of prior authorization mandates, including significant impacts on patient health such as disease progression (80%) and loss of life (36%). The most widely cited harms to patients reported were delays in treatment (96%) and diagnostic imaging (94%); patients being forced onto a second-choice therapy (93%) or denied therapy (87%); and increased patient out-of-pocket costs (88%).

The survey responses also reflected the difficulties of the prior authorization mandates. Nearly all respondents report experiencing burdensome administrative requirements, delayed payer responses, and a lack of clinical validity in the process. The survey also found that on average:

- It takes a payer five business days to respond to a prior authorization request.
- A prior authorization request is escalated beyond the staff member who initiates it 34% of the time.
- Prior authorizations are perceived as leading to a serious adverse event for a patient with cancer 14% of the time.
- Prior authorizations are "significantly" delayed (by more than one business day) 42% of the time.

Over the past several years, Members of Congress have become increasingly concerned about the use of prior authorization in MA plans. The House of Representatives unanimously passed the *Improving Seniors' Timely Access to Care Act* (S. 3018/H.R. 3173) in September 2022. This bipartisan legislation,

developed with input from ASCO, finished the 117th Congress with 380 combined cosponsors — 53 senators and 327 representatives — supporting the legislation. Importantly, more than 500 organizations representing patients, health care providers, the medical technology and biopharmaceutical industry, health plans, and others endorsed the legislation.

While the legislation did not pass the Senate last Congress, ASCO is optimistic that the CMS Electronic Prior Authorization proposed rule, which was published in the Federal Register on December 13, 2022, takes steps to improve the prior authorization requirements that will improve beneficiary access to necessary and lifesaving services and ease the administrative burden on physicians and payers. This rule aligns with many of the provisions included in the legislation, which, if passed, would have gone into effect in 2024.

Both this proposed rule and the legislation:

- Establish an electronic prior authorization program.
- Standardize and streamline the prior authorization process.
- Increase transparency around MA prior authorization requirements and their use.

We strongly urge CMS to address two overarching concerns with the proposed rule to maintain current regulatory and legislative momentum to address prior authorization:

1. Expedite the implementation timeline of provisions finalized in this rule for all plans and require compliance with finalized proposals in contract year 2024.
2. Include drugs—which are currently excluded—in the electronic prior authorization program and application programming interface (API) requirements.

ASCO appreciates the 233 Representatives and 61 Senators who signed letters, including 23 members of the Energy and Commerce Committee, to CMS urging the agency to finalize and implement the proposed rule, as well as urging CMS to expand on the rule to allow for some real-time electronic prior authorization decisions, require a response within 24 hours for urgently needed care, and increase transparency.

ASCO appreciates the inclusion of the *Improving Seniors' Timely Access to Care Act* in this hearing and looks forward to continuing to work with the Subcommittee members to address this burdensome issue plaguing our health care system.

Real-Time Benefit Accessibility

Provider accessibility to real-time benefit information plays a critical role in timely care delivery. ASCO supports the proposal led by Rep. Arrington *to promote provider choice using real-time benefit information.* Specifically, ASCO supports a "real-time benefit tool (RTBT)" that allows insurers to electronically send formulary and benefit information to prescribing clinicians, using technology that integrates with clinicians' electronic prescribing and electronic health record (EHR) systems. Such transactions, when integrated into qualified EHRs, could increase efficiencies. ASCO also supports awarding credit to physicians using RTBTs under MIPS.

Telehealth Privacy

Telehealth has served as an essential resource in cancer care delivery, especially for those in rural and underserved communities. ASCO appreciates Congress' extension of telehealth flexibilities and allowance of services under Medicare through 2024. As Medicare continues to regulate telehealth services, we are concerned with specific privacy gaps for providers. Specifically, Medicare recently proposed requiring providers to include their home addresses on Medicare enrollment forms if telehealth services are performed at their homes. To protect provider information, we support the *Telehealth Privacy Act of 2023*, which is up for discussion in this hearing. The legislation would prohibit Medicare from making provider's home addresses publicly accessible.

Patient Access to Treatments

In addition, ASCO is concerned about the increasing barriers for patients to access their treatments. Some oncology practices have in-office pharmacies, allowing physicians to trust that their patients receive intended drug treatment with appropriate instructions. If a patient is unable to come to the office, a physician should be able to mail or otherwise send a prescription securely to a patient or have a trusted surrogate pick up prescriptions on behalf of the patient. Studies[7] have shown that integrated pharmacy services may increase patient adherence to medication. However, a CMS determination[8][9] states that delivery of medicine to a patient using the U.S. Postal Service or other trusted service violates the in-office exception of the Stark Law.

We support and appreciate the Subcommittee's consideration of the *Seniors' Access to Critical Medications Act of 2023* (H.R. 5526), which aims to clarify the in-office ancillary services exception to the physician self-referral law to allow drugs to be mailed to Medicare patients. This bipartisan legislation would clarify that a surrogate may deliver medicine dispensed at a physician-owned pharmacy without violating the law. This critical legislation will reduce patient barriers to treatment and allow patients and providers to focus on the treatment plan.

Conclusion

Thank you for your commitment to improving the Medicare program and cancer care delivery. ASCO stands ready to serve as a resource as you continue this much needed dialogue around reforms to the physician reimbursement system. Please contact Megan Tweed at Megan.Tweed@asco.org with any questions.

[7] Iuga A, & McGuire M. Adherence and health care costs. Risk Manag Healthc Policy. 2014; 7: 35–44.
May B. ASCO/NCODA Release Standards for Medically Integrated Dispensing of Oral Anticancer Drugs. The ASCO Post. December 25, 2019. https://ascopost.com/issues/december-25-2019/asconcoda-release-standards-for-medically-integrated-dispensing-of-oral-anticancer-drugs/

[8] Centers for Medicare & Medicaid Services. Physician Self-Referral. (2023). https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/index

[9] CMS Physician Self-Referral Law FAQs. https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQs-Physician-Self-Referral-Law.pdf