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Board Chair
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Statement prepared for:
House Committee on Small Business Subcommittee on Oversight, Investigations, and Regulations
Burdensome Red Tape: Overregulation in Health Care and the Impact on Small Businesses

July 19, 2023

The Association for Clinical Oncology (ASCO) is pleased to submit this statement for the record of the hearing entitled, "Burdensome Red Tape: Overregulation in Health Care and the Impact on Small Businesses." ASCO appreciates that the Subcommittee is holding today's hearing and has provided this opportunity to address the administrative burdens that threaten oncologists' ability to deliver high-quality cancer care that patients deserve.

ASCO is a national organization representing more than 45,000 physicians and other health care professionals who care for people with cancer, including many who run their own practices. 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.

Step Therapy
Step therapy is a utilization management tactic often referred to as "fail first," where patients are required by their insurance provider to try and fail medications chosen by a payer before the payer will cover the medication originally prescribed by the patient's health care provider. Step therapy policies are generally inappropriate for use in oncology due to the individualized nature of modern cancer treatment and the lack of interchangeable clinical options. Step therapy can lead to disease progression and irreversible damage to a cancer patient's health, undermines and threatens the doctor-patient relationship, and further exacerbates health inequities.

ASCO joined other organizations on a letter to the Centers for Medicare and Medicaid Services (CMS) regarding the 2024 Medicare Advantage Plan and Part D Rule, urging CMS to move swiftly to reinstate the step therapy prohibition in Medicare Advantage (MA) plans for Part B drugs as described in the September

17, 2012, memo *Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services.* ASCO is concerned that CMS asserts in this proposed rule that, "the requirements in the 2019 rule, in combination with current MA program regulations, ensure access to Part B drugs and limit the potential for step therapy policies to interfere with medically necessary care." We respectfully disagree that the current allowances made for step therapy in Medicare Part B meet this standard, instead creating unnecessary burdens and irreparable consequences when it comes to the health and wellness of patients. We continue to urge the administration to protect patients' access to care and expeditiously reverse the harmful decision to allow MA plans to implement step therapy.

Additionally, ASCO has endorsed the *Safe Step Act* (H.R. 2630/S. 652), led by Representatives Brad Wenstrup (R-OH), Raul Ruiz, MD (D-CA), Mariannette Miller-Meeks, MD (R-IA) and Lucy McBath (D-GA) and Senators Lisa Murkowski (R-AK), Maggie Hassan (D-NH), Roger Marshall, MD (R-KS), and Jacky Rosen (D-NV). This legislation puts important patient safeguards from step therapy protocols in place for ERISA-governed health plans by requiring exceptions when the treatment is contraindicated, expected to be ineffective, likely to cause adverse reaction, or the patient is stable on treatment already selected.

Specifically, the legislation would require employer sponsored health plans to:

- Establish a clear and convenient process for physicians to appeal a step therapy protocol.
- Make information on the appeals process readily available on the plan's website, including the exception requirements and any necessary forms and contact information.
- Grant patient exceptions to step therapy under five critical circumstances.
- Expedite care by requiring a timely decision for appeals — 72 hours, or within 24 hours if life threatening.

ASCO urges Congress to pass the *Safe Step Act* to ensure that patients have access to effective and timely treatments, and that physicians are able to decide the right treatment for their patients at the right time.

Prior Authorization

An ongoing source of frustration across the oncology care team is overly burdensome prior authorization requirements. ASCO recently published the results of a survey of our members in the United States 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 move forward 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 in order 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 more than 230 Representatives and 61 Senators who signed letters to CMS urging the agency to finalize and implement the proposed rule, as well as urges 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.

Copay Accumulators

In addition to prior authorization and step therapy, copay accumulators are another utilization management technique that has a negative impact on providers, their practices, and their patients.

In recent years, health insurance companies, employers, and pharmacy benefit managers (PBMs) have shifted costs for specialty prescription medicines to patients. To help patients afford the cost of their prescriptions, pharmaceutical manufacturers or charitable organizations often offer copayment assistance, which can reduce or eliminate the patient share of payment for medications. This has led to a

rise in insurers and PBMs implementing "copay accumulator" programs, which can negate the intended benefit of patient assistance programs, remove a financial safety net for patients who need specialty medications, and result in increased out-of-pocket costs and poorer health outcomes.

Copay accumulators prevent patient assistance funds from applying toward a patient's annual out-of-pocket maximum or deductible, lack transparency, increase costs for patients, result in poorer health outcomes, and increase administrative burden for providers.

The *Help Ensure Lower Patient (HELP) Copays Act* (H.R. 830/S. 1375), led by Representatives Buddy Carter (R-GA-1), Nanette Diaz Barragan (D-CA-44), Mariannette Miller-Meeks, MD (R-IA-1), and Diana DeGette (D-CO-1) and Senators Tim Kaine (D-VA) and Roger Marshall, MD (R-KS), would prohibit the use of copay accumulators and require health plans and PBMs to count the value of copay assistance toward a patient's cost-sharing requirements. ASCO urges Congress to pass the *HELP Copays Act* to protect patients from harmful insurance and PBM practices that raise patient out-of-pocket drug costs.

Administrative Burden and Burnout

Oncology care teams face significant clinician burnout, leading to early retirement or individuals leaving the field. Burnout in oncology has been linked to provider shortages and the increased demand for health care services from an aging population. Providers of all types, including those working in small practices, report stress and burnout directly stemming from increased administrative and financial burdens from payer policies, such as prior authorization, step therapy, and copay accumulator programs.

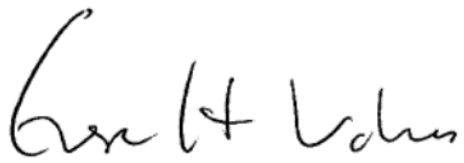
PBM policies are also contributing to workforce burnout. Data collected during the 2018 ASCO Practice Survey showed PBMs may reduce access and quality of care while increasing burdens on providers. For example, three-quarters of practices surveyed said PBMs interfered with patient care and/or made it difficult to deliver care, and 56% say that PBMs disrupted practice workflow. The significant erosion of time spent delivering care stands in direct opposition to the most common reason clinicians cite as their motivation for entering practice: helping patients.

To address burnout and support small practices, ASCO recommends continued federal investments for programs authorized under the *Dr. Lorna Breen Health Care Provider Protection Act* that aid physicians in combatting and coping with burnout in the workplace. ASCO also recommends enactment of policy solutions to address administrative burdens, which impede the delivery of quality patient care and lead to burnout. Legislative solutions include the previously mentioned *Safe Step Act* (H.R. 2630/S. 652) and the *Help Ensure Lower Patient (HELP) Copays Act* (H.R. 830/S. 1375), as well as the *Pharmacy Benefit Manager Transparency Act* (S. 127). Advancement of pending regulatory solutions under CMS on prior authorization could also reduce burdens for providers.

Finally, ASCO consistently opposes the imposition of any mandatory demonstration projects on oncology practices, particularly those that carry significant risk of harm to patients with cancer. We will continue to urge the Centers for Medicare and Medicaid Innovation (CMMI) not to adopt mandatory models of any nature.

ASCO is pleased to serve as a resource to you and your colleagues as you continue to investigate overly burdensome regulations that are impacting ASCO members and their practices. Should you have any follow-up questions or concerns, please do not hesitate to contact Katie Gifford at katie.gifford@asco.org.

Sincerely,



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