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June 15, 2026

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20001

Submitted electronically at www.regulations.gov

Re: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges (CMS-0062-P) [RIN 0938-AV44]

Dear Administrator Oz,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule that was published in the Federal Register on April 14, 2026.

ASCO is a national organization representing more than 50,000 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.

ASCO commends the agency for taking steps to improve the prior authorization process for drugs and believes the changes and recommendations discussed below will improve beneficiary access to necessary and life-saving services while easing the administrative burden on physicians and payers.

Although tools like prior authorization can play a role in managing cost when implemented appropriately and transparently, we urge the agency to avoid policies that restrict or delay access to cancer care. ASCO members have repeatedly raised concerns about prior authorization as a barrier to appropriate care. In our updated position statement on prior authorization, "ASCO Position Statement: Prior Authorization" we outline recommendations to facilitate appropriate implementation of prior authorization policies.[1] Our position statement on the use of artificial intelligence in prior authorization outlines recommendations to protect against the potential negative impacts that AI could have on the prior authorization process.[2]

We are pleased to offer our comments on select provisions included in the proposed rule.

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Electronic Prior Authorization for Drugs

ASCO strongly supports CMS's proposal to require impacted payers to incorporate coverage and documentation requirements into the Prior Authorization API to support electronic prior authorization for drugs covered under a medical and/or a pharmacy benefit by October 1, 2027.

A significant portion of cancer treatment requires patient access to life-saving drugs and the prior authorization requirements associated with these drugs are extremely burdensome for oncologists and their patients. Time-consuming, labor-intensive prior authorization processes adds significant burden on patients and providers. While many prior authorization requests may be initiated electronically via individual payer portals, subsequent interactions and requests for additional information are frequently conducted via fax or phone, leading to delayed communication, slower response times, and delays in patient care. These additional requirements and interactions drive the need for staff dedicated to processing and responding to prior authorization requests. We commend the agency for taking steps to require electronic prior authorization among several payers for drugs under both a medical and pharmacy benefit.

Improving Communications for Prior Authorizations

ASCO strongly supports CMS's proposal to require State Medicaid and CHIP fee-for-service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and qualified

[1] https://cdn.bfldr.com/KOIHB2Q3/as/2vpsrm6s863m3q6zmg9p3rcx/2022-Prior-Auth-Position-Statement
[2] https://cdn.bfldr.com/KOIHB2Q3/as/z9m6shzn9xcfjc52n7cwqh6/2025-ASCO-Position-Statement-AI-Prior-Auth

health plan (QHP) issuers on the federally-facilitates-exchanges (FFEs) to communicate to providers a specific reason for denying a prior authorization request for any drugs, regardless of the method used to send the prior authorization request or decision. (Medicare Advantage plans are currently subject to this requirement.)

ASCO strongly supports CMS' proposal to require impacted payers to provide a specific reason that helps a provider to understand why the prior authorization request for drugs was denied and what actions must be taken to resubmit or appeal the decision. Providers report that when receiving a prior authorization denial, often the reason for the denial is unclear. Failure to provide a detailed response with clear, specific reasons for the denial requires additional follow-up and only worsens an already heavy administrative burden on physicians and their staff.

Many payers give status updates that simply read, "pending," with no indication of what further information might be needed for a final decision. An explanation of the cause of the delay and the information anticipated to be needed for a final decision would help to streamline the process. Providers have noted that this lack of specific feedback earlier in the process plays a significant role in persistent denials for lack of relevant information, and that this same information provided later in the process often overturns a denial.

Improving Decision Timeframes for Non-Drug Items and Service Prior Authorizations

ASCO supports CMS's proposal to require QHP issuers on the FFEs to provide notice to the requesting provider of prior authorization decisions as expeditiously as the enrollee's health condition requires, but no later than seven calendar days after receiving a standard prior authorization request and no later than 72 hours after receiving an expedited request for non-drug items and services.

ASCO supports CMS's proposal to shorten decision timeframes for non-drug items and services within QHP plans on the FFEs to align with the other impacted payers subject to electronic prior authorization requirements. ASCO's comments in response to the 2024 proposed rule had urged CMS to align QHP timeframes with other payers. Medically appropriate cancer care demands patient access to the most appropriate care at the most appropriate time, regardless of the type of insurance coverage. Patients who have purchased health care coverage on the Exchanges should not have to accept longer wait times for a prior authorization request.

Improving Decision Timeframes for Drug Prior Authorizations

To ensure prompt notification and align prior authorization decision processes across different CMS programs, CMS proposes that certain payers be required to provide notice of drug-related prior authorization decisions within specific timeframes.

- State Medicaid FFS programs, Medicaid managed care plans, and CHIP managed care entities would be required to make prior authorization decisions for all drugs within a timeframe that aligns with existing decision timeframe requirements for covered outpatient drugs, no later than 24 hours after receiving a prior authorization request.
- State CHIP FFS programs would be required to provide notice of a prior authorization decision no later than 24 hours after receiving a prior authorization request for any prescription drugs for which Federal Financial Participation (FFP) is available.
- QHP issuers on the FFEs would be required to provide notice of a prior authorization decision to the requesting provider as expeditiously as the enrollee's health condition requires, but no later than 72 hours after standard prior authorization requests and no later than 24 hours for expedited prior authorization requests for all drugs.

ASCO supports the shortened near-term timeframes for prior authorization requests; however, we urge CMS to expedite the transition toward true, real-time decision-making. Oncology workflows rely on tightly synchronized, multi-modal regimens where a delay in a single component can derail an entire treatment plan. For example, in neoadjuvant settings, chemotherapy or radiation must occur within a strict window to maximize resectability and pathological complete response. When a prior authorization request stalls for multiple days, it creates a cascading operational delay across medical, radiation, and surgical oncology. This not only threatens adherence to evidence-based protocols and compromises patient outcomes, but it also disrupts high-demand resources—such as surgical slots and radiation simulation blocks—creating a bottleneck that impacts care delivery across the entire clinic.

CMS is not proposing any changes to timeframes for Medicare Advantage plans. Under current regulations, MA plans must notify the enrollee and the prescriber as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving a standard request and no later than 24 hours after receiving an expedited request. **ASCO urges CMS to initiate future rulemaking requiring MA organizations to respond to *all* drug prior authorization requests within 24 hours, aligning with Medicaid and CHIP requirements for covered outpatient drugs.**

In comments on the previous proposed rule, ASCO raised concerns with the lack of consequences when a payer does not comply with required timeframes. Payer failure undermines the intent of the interoperability and electronic prior authorization regulations and only makes the burden more egregious on providers and reinforces the current burden associated with prior authorization. Furthermore, it provides little incentive for payers to implement interoperability and electronic prior authorization process improvements. Payers need to be held accountable and provide prior authorization notifications within the set timeframe. **If the physician does not receive a decision within the set timeframe, the default response should be an approval of the prior authorization request and guaranteed reimbursement of the item, service, or drug. We strongly urge CMS and other regulatory agencies to hold payers accountable for the timeliness of prior authorization determinations.**

Transparency Requirements:

The 2024 final rule requires that impacted payers annually report prior authorization metrics for non-drug items and services on their public websites. CMS is proposing to add requirements for impacted payers to report the numeric counts in addition to percentages for certain existing metrics, as well as for impacted payers to publicly report additional prior authorization metrics on non-drug items and services. These proposed requirements would begin on the effective date of the final rule.

CMS is also proposing that Medicaid managed care plans and CHIP managed care entities report prior authorization metrics for non-drug items and services finalized in the 2024 final rule, as well as prior authorization metrics for non-drug items and services introduced in this proposed rule at both the program and plan levels no later than 90 days after the end of their contract rating period, beginning on the effective date of the final rule.

In addition, CMS proposes to require impacted payers to annually report prior authorization metrics for drugs on their public websites. The proposed compliance dates for reporting these new metrics are in 2028 for data from the 2027 reporting period.

ASCO supports the proposals and reporting adjustments that CMS is proposing; however, we believe the required reporting metrics should be available at the most granular level. Aggregating these data across all items, services, and drugs may fail to provide meaningful and actionable information for specific specialties, patients undergoing complex treatments, CMS, and other stakeholders. A better approach would be for the plan to provide specific data points related to certain specialties, such as oncology treatment. Without more granular information, we are concerned that the data will be too broad to show how often specific treatments and

services are impacted by payer policies and CMS will be unable to effectively monitor the adverse impact of plan prior authorization policies, including suboptimal clinical outcomes, increases in adverse events and disparities in treatments.

Any patient or provider, as well as all other interested parties, should have meaningful access to prior authorization information metrics, including whether prior authorization is required, and if so, the number of times the request for a particular service or drug has been denied, approved, or approved after appeal. The information should be available immediately at the most granular level at an individual's request. An individual should be able to query a search function and return the information they are looking for at the level of aggregation they request.

In addition to posting the prior authorization metrics on the payer website, ASCO urges CMS to require payers to report these data directly to CMS. Payers have immense flexibility in how and where they publish data. Direct reporting to CMS could promote machine-readable, uniform, and standardized data into a single, centralized federal database. It could also prevent payers from hiding poor performance metrics behind complex website navigation or non-standardized reporting formats. Centralized reporting would allow CMS to benchmark insurers, identify outliers with disproportionately high denial or appeal-reversal rates, and flag entities frequently utilizing maximum review extensions. Without direct reporting, federal enforcement becomes reactive—relying on provider complaints rather than proactive, data-driven systemic audits. Centralizing the data would help provide patients and healthcare providers with side-by-side, apple-to-apples comparisons of how reliably and quickly a payer approves necessary medical care.

Operational Barriers to Electronic Prior Authorization

Although we support CMS's proposal, we want to highlight an operational barrier that physicians and other cancer care providers may encounter when patients are seen in multiple clinics or settings, which is common in the current cancer care delivery system. A patient's care pathway is rarely confined to a single clinic. For instance, a community practitioner, using one electronic health record (EHR), may order a therapeutic regimen and refer the patient to a hospital-based infusion center or facility, using a different EHR, to perform the treatment or drug administration. When distinct clinical sites use different EHR systems that do not seamlessly communicate, two problems occur.

First, when required documentation resides in a different EHR, the servicing provider cannot easily retrieve it to submit an electronic prior authorization. This forces staff into manual

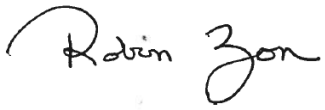
workflows to acquire the data, delaying the process. Consequently, because providers cannot supply this external documentation immediately, payers cannot meet the 24-hour turnaround timeframe.

Secondly, it is unclear which entity is ultimately responsible for securing the prior authorization: the ordering physician who has the clinical documentation and medical decision making to support the medical necessity, or the performing provider who provides the services and reports for reimbursement. CMS must account for systemic, multi-EHR data sharing barriers before penalizing clinicians under the Merit-based Incentive Payment System (MIPS) for failing to meet the electronic prior authorization Promoting Interoperability measures when the underlying technology fails to support cross-facility care coordination.

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We appreciate CMS's efforts to streamline the burdensome prior authorization process and the Agency's efforts to ensure that drugs are included in this streamlined process. Thank you for the opportunity to comment on the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule. Please contact Gina Hoxie (gina.hoxie@asco.org) with any questions or for further information.

Sincerely,



Robin Zon, MD, FASCO
Chair of the Board
Association for Clinical Oncology