ASTCT®
American Society for
Transplantation and Cellular Therapy

June 12, 2026

Dr. Mehment Oz
Administrator
Department of Health and Human Services
Centers for Medicare & Medicaid Services
CMS-0062-P, P.O. Box 8013
Baltimore, MD 21244–8013
Delivered electronically at regulations.gov

RE: CMS-0062-P 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

Dear Administrator Oz:

The American Society for Transplantation and Cellular Therapy (ASTCT) is an international professional membership association of more than 3,900 physicians, investigators, and other health care professionals from more than 50 countries. Our mission is to advance hematopoietic cell transplantation and cellular therapies through groundbreaking research, high-quality education, impactful advocacy, and clinical excellence.

ASTCT's comments on the 2026 CMS proposed rule for Interoperability Standards and Prior Authorization for Drugs focus on the applicability of the requirements to out-of-network and out-of-state providers, the importance of denial specificity, improvements to appeals and peer-to-peer review processes, and the need for effective enforcement and operational oversight of both the proposed and previously-finalized requirements. We commend the agency on the many proposed policy changes in this year's proposed rule. We particularly appreciate CMS's commitment to improving interoperability, reducing provider burden, simplifying prior authorization requirements, and ensuring beneficiaries have timely access to needed care.

Sincerely,

Margaret L. MacMillan, MD, MSc, FRCPC
ASTCT President 2026-2027

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Applicability to Out-of-Network or Out-of-State Providers

ASTCT requests clarification regarding the applicability of the proposed requirements to out-of-network or out-of-state providers (for Medicaid) when a therapy is not otherwise available to a patient via their in-network or in-state care options. Specialized cell therapy treatments are used for uncommon but life-threatening illnesses, like blood cancers, and are available at a limited number of treatment sites. As such, ASTCT patients frequently require access to highly specialized centers outside of their payer's network and/or the patient's state. Consequently, these patients face unique access challenges when payers delay prior authorization (PA) determinations or deny these authorizations altogether due to network or in-state care requirements, even if the denial is later overturned.

For example, while a National Coverage Determination (NCD) for Chimeric Antigen Receptor T-cell therapy (CAR-T) exists, there is no network adequacy standard for MA plans which would require them to have hospitals that provide this and other cellular therapies in-network. As such, MA beneficiaries may face administrative blocks from the care they have a right to receive, given the issuance of an NCD, simply because the provider they need to access is not a part of their plan's network. ASTCT is concerned that inconsistent application of requirements could create operational gaps, additional administrative burden and, most importantly, cause clinically significant delays in care.

Access to specialty cell therapy should not be determined by chance and geography. When a treatment center is unavailable within a patient's state or contracted network, those patients will experience substantially different clinical outcomes compared with individuals who have local/in-network access to a treatment center. CMS has an opportunity to change those outcomes by imposing uniform PA requirements on payers when a therapy is medically necessary but not available in-network or in-state.

ASTCT requests that CMS clarify that PA standards, transparency requirements, and interoperability obligations apply consistently when payers authorize out-of-network care or when it is determined that a medically necessary service is unavailable within the state for a Medicaid beneficiary.

CMS should also provide clear operational guidance for payer-provider communications and workflows related to requests for out-of-network or out-of-state care. Such guidance will help ensure that providers can initiate these requests directly and that administrative processes do not create unnecessary barriers that delay or impede authorization for medically necessary out-of-network or out-of-state services.

Specificity of Denial Reasons

ASTCT strongly supports CMS's proposal to require greater specificity regarding PA denials. Providers and patients frequently receive denial communications that are vague and do not include enough detail to support appeal efforts.

ASTCT recommends that CMS require plans to distinguish between medical necessity denials, administrative denials, and network or site-of-care denials. Additionally, payers should be required to provide references to payer policies that were used to make the decision, as well as a direct link to the medical and administrative policies used in their decision making.

Greater transparency would enable providers to make more-informed decisions about whether to appeal a request. This will, in turn, improve their ability to pursue appeals, when justified, and reduce unnecessary appeals when sufficient grounds do not exist. The addition of clear denial type and rationale would create efficiencies for both payers and providers.

Improving Appeals and Peer-to-Peer Processes

ASTCT urges CMS to clarify whether reconsideration and appeals processes are subject to the timeliness and transparency requirements outlined in this proposed rule. Providers frequently report that their requests for complex and highly specialized care, such as cellular therapies and transplant procedures, are subject to prolonged review periods, delays in scheduling peer-to-peer consultations, and "peer" reviews conducted by individuals who lack the appropriate clinical expertise to evaluate these cases. For CMS' proposed improvement to drive efficiencies and increase patient access, peer-to-peer and appeals processes must be refined as well.

Enforcement and Operational Oversight

ASTCT urges CMS to develop additional enforcement mechanisms to support both existing and future PA reforms. Without consistent and meaningful enforcement, the practical effectiveness of these reforms will be limited, particularly for those requirements related to decision timelines and denial specificity. Our members have reported that noncompliance with Medicaid's Covered Outpatient Drug (COD) 24-hour determination requirement has significantly undermined the effectiveness of the rule.

While ASTCT supports the proposed public reporting requirements and believes they may encourage greater compliance, public reporting alone is unlikely to ensure adherence to these standards. For this reason, CMS should establish a clear process for reporting noncompliance and should implement meaningful consequences for plans that fail to meet regulatory requirements. Such accountability measures are necessary to translate these reforms into tangible improvements for patients and providers, and to inform future policy-making efforts.

Conclusion

ASTCT greatly appreciates CMS' efforts to ensure that Medicare Advantage (MA) organizations, state Medicaid fee-for-service (FFS), state Children's Health Insurance Program (CHIP) FFS programs, Medicaid managed care plans, CHOP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFEs), including issues that offer small group market QHPs on the Federally-faciliated Small Buisness Health Opetions Program (FF-SHOP) Exchanges provide timely and clear communication back to hospitals and providers. ASTCT thanks CMS for the opportunity to provide comments on this rule. We stand ready to discuss any aspect of our comments further with your staff.

Please send any correspondence to ASTCT Director of Government Relations, Molly Ford, at *MFord@astct.org*.