ASTCT
American Society for
Transplantation and Cellular Therapy

May 12, 2025

Russell T. Vought
Director, Office of Management and Budget
725 17th St NW
Washington, DC 20503

RE: OMB Request for Information: Deregulation, *OMB-2025-0003*

Submitted electronically at www.regulations.gov

Dear Mr. Vought,

The American Society for Transplantation and Cellular Therapy (ASTCT) is a professional membership association of more than 3,900 physicians, scientists, and other health care professionals promoting hematopoietic stem cell transplantation (SCT) and cellular therapy through research, education, scholarly publication, and clinical standards. Our Society's clinical teams have been instrumental in developing and implementing clinical care standards and advancing cellular therapy science, including participation in trials that led to current Food and Drug Administration (FDA) approvals for chimeric antigen receptor T-cell (CAR-T) therapy and hematopoietic stem cell (HSC) gene therapies for genetic immune system and blood disorders. ASTCT appreciates our prior conversations and collaboration with CMS regarding coverage and payment for these new therapies.

ASTCT welcomes the opportunity to submit our concerns about regulations that create unnecessary and significant burdens to providing innovative and potentially life-saving care to Medicare beneficiaries with blood cancers. Today, we wish to raise two significant barriers to care that have simple solutions:

1) **Require state Medicaid programs to recognize active Medicare enrollment in lieu of individual state enrollment requirements; and**
2) **Make modifications to Medicare telehealth requirements to allow beneficiaries to receive specliaized care without creating unnecessary risks to their health.**

Simplify Medicaid provider enrollment requirements

The clinical services ASTCT's members provide are highly specialized and are only available at a limited number of hospitals. For many patients, there may not be an in-state provider of these services or the in-state provider may be many hours from their home – in these cases, Medicaid patients need to seek care at alternate facilities, which requires out-of-state providers to enroll in the patient's local Medicaid program.

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ASTCT acknowledges that Medicaid provider enrollment requirements are designed to protect program integrity and ensure that Medicaid beneficiaries receive safe care from qualified and eligible providers. But hospitals and providers attempting to work through these extreme, complex and administratively burdensome requirements are often unable to successfully navigate the requirements on behalf of their patients.

In order to be paid by a state's Medicaid program for any services rendered to a Fee-for-Service or a managed care organization beneficiary, a hospital and all providers involved in a beneficiaries' care MUST be enrolled in the patient's Medicaid program. Providers and centers routinely enroll in their home state's Medicaid program; however, it is administratively impossible to do for all 50 state programs because each functions independently and has its own enrollment requirements. Furthermore, there are no federal requirements mandating timely enrollment; so, even after providers apply for enrollment, beneficiaries could still be forced to wait many months before proceeding with treatment, because the state Medicaid program is still processing the applications.[1]

State Medicaid programs should be required to accept active enrollment with the Medicare program in lieu of individual state enrollment requirements. Enrollment should be mandated to occur within 30 days of a provider's initial request, or as expeditiously as the beneficiaries' medical condition requires, whichever is shorter. ***Put more simply, requiements in place for the Medicare enrollment process should be sufficient for Medicaid.*** If implemented, this would eliminate unnecessary barriers to access and ensure that beneficiaries get the life-saving care they need in a timely manner and reduce burdensome paperwork for hospitals and physicians. **We ask that OMB require the CMS Center for Program Integrity and Provider Enrollment and Oversight Group to make this change immediately.**

Support permanent use of telehealth for all Medicare beneficiaries

ASTCT greatly appreciates the extent to which CMS was able to use its Public Health Emergency authority to extend and augment the availability of telehealth and similar services for Medicare beneficiaries over the past several years. We understand that CMS' authority will sunset on October 1, 2025 unless the legislation is extended or another solution is implemented. Making telehealth permanently available to all Medicare beneficiaries will create more efficient and uniform access to care and will reduce unnecessary burdens on the health care system created by having to treat groups of Medicare beneficiaries differently from the rest.

CMS acknowledged the need for continued telehealth access in the CY 2025 Medicare Physician Fee Schedule Final Rule, saying the following -

> *We recognize that there are significant concerns about maintaining access to care through the use of Medicare telehealth services with the expiration of the statutory*

[1] Centers for Medicare & Medicaid Services (CMS), Medicaid Provider Enrollment Compendium (MPEC), Baltimore (MD): CMS, March 22, 2021. Online: https://www.medicaid.gov/sites/default/files/2021-05/mpec-3222021.pdf.

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> *flexibilities that were successively extended by legislation following the PHE for COVID–19.* ***We understand that millions of Medicare beneficiaries have utilized interactive communications technology for visits with practitioners for a broad range of health care needs for almost 5 years****. We are seeking comment from interested parties on our understanding of the applicability of section 1834(m) of the Act to the new telemedicine E/M codes, and how we might potentially mitigate negative impact from the expiring telehealth flexibilities, preserve some access, and assess the magnitude of potential reductions in access and utilization.*[2]

ASTCT wishes to emphasize that not only have beneficiaries grown accustomed to this access, but also that these access options have a direct positive impact on the health and well-being of beneficiaries and their caregivers. The clinical services that ASTCT members provide (e.g., stem cell transplantation, stem-cell-based gene therapies, and cellular therapies like CAR-T) are highly specialized services provided at limited locations. Patients usually travel long distances to receive these therapies, and frequently need to temporarily relocate during the extensive course of treatment. The availability of telehealth and other communication services has greatly increased access to specialist teams for purposes of post-treatment concerns and monitoring once beneficiaries are back at their homes. Our members have also noted that the availability of virtual options decreases infection risk to these patients, as they are significantly immunocompromised after treatment and supports caregivers in returning to work and/or other commitments.

The expiration of most telehealth services will have detrimental effects on the patient population we serve. It may mean that some patients face challenges in obtaining the care they need from providers with the specialized expertise necessary to treat them appropriately. It will likely increase financial burden and toxicity, as patients and caregivers need to resume frequent travel far from their homes, typically on limited incomes.

Transplant and cell therapy clinicians are often located in hospital departments (i.e., the hospital is the distant site) when they furnish telehealth services to patients in homes and other originating sites. The technology, space, and ancillary staff support are provided by hospital employees and reported as hospital costs. The ability of our facility-based clinicians to furnish care via telehealth is vital to our patient population due to the distances they may have to travel to a qualified center and their compromised immunity during transplant and cell therapy treatment.

Specially, ASTCT suggests the following changes:

Remove telehealth originating site restrictions within the Medicare program at Sec. 1834(m)(4)(C)(ii)(X) of the Social Security Act (42 U.S.C. 1395m) and 42 CFR 410.78(b)(3) to enable patients to receive telehealth in their homes. Under current rules, patients must be in

[2] CMS, CY 2025 Medicare Physician Fee Schedule Final Rule. Online: https://www.govinfo.gov/content/pkg/FR-2024-12-09/pdf/2024-25382.pdf (p. 97793)

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a clinical site of care, which completely undermines the value of telehealth for patients, limits its adoption and adds costs for providers.

Remove telehealth geographic site restrictions within the Medicare program at Sec. 1834(m)(4)(C)(i) of the Social Security Act (42 U.S.C. 1395m) and 42 CFR 410.78(b)(4) to enable beneficiaries in non-rural areas to have the same access to virtual care as those in rural areas.

Eliminate the telehealth physician home address reporting requirement, which is currently under waiver as referenced at 89 FR 97110. Without continued waivers or removal, telehealth providers must list their home address on publicly available enrollment and claims forms when performing telehealth services from their homes, compromising their privacy and safety.

Thank you for the opportunity to submit these suggestions for deregulation. For more information, please contact Alycia Maloney, ASTCT's Director of Government Relations, at amaloney@astct.org.

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2025-2026

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