

July 20, 2026

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850
Submitted electronically via the Regulations.gov

RE: Medicaid Managed Care State Directed Payments and Medicaid Fee-For-Service Targeted Medicaid Practitioner Payments (CMS-2449-P)

Dear Administrator Oz:

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

ASTCT appreciates the efforts the Centers for Medicare & Medicaid Services (CMS) has made to improve monitoring, oversight, and transparency of SDPs. We propose the following three key recommendations to consider for the Final Rule.

- CMS should preserve state flexibility for cell and gene therapy treatment centers by allowing exceptions or alternative SDP payment limit methodologies for cell and gene therapy (CGT) treatment centers.
- CMS should evaluate the impact of Medicare-based SDP payment limits on Medicaid beneficiary access to CGTs.
- CMS should clarify that New Technology Add-on Payment (NTAP) and outlier payments should be included in the Medicare-based SDP payment calculation.

We very much appreciate your consideration of our comments. Please contact Molly Ford, ASTCT's Director of Government Relations, as needed, at mford@astct.org.

Sincerely,



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

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Executive Summary

The following summarizes ASTCT's recommendations, which are set out in full in the detailed comments below.

1. State Directed Payments in Medicaid Managed Care (§ 438.6)

- Preserve state flexibility by allowing exceptions or alternative payment limit methodologies for CGT treatment centers, academic medical centers, and children's hospitals where Medicare payment rates are unavailable or do not adequately reflect the cost of delivering these therapies.
- Measure compliance with the payment limit in the aggregate, consistent with FFS upper payment limit principles, rather than on a per-service or per-discharge basis.
- Preserve states' existing flexibility to define their own provider classes and decline to impose either a narrower federal definition or a broad, uniform category encompassing all hospitals or all outpatient services.
- Conduct and publicly report an analysis of how the Medicare-based payment limits would affect Medicaid beneficiary access to CGTs, including effects on network adequacy, provider participation, treatment center capacity, and geographic access, before finalizing the rule.

2. Comment Solicitation on the Definition of the Total Published Medicare Payment Rate

- To the extent the payment limit applies to cost-exempt providers at all, support CMS's proposed treatment of their cost-based reimbursement as the Medicare rate as the only defensible benchmark, subject to the exceptions ASTCT recommends, and urge CMS to reject the two alternatives it considered, both of which would set the limit below cost.
- Confirm that NTAP and outlier payments are incorporated into the total published Medicare payment rate and provide illustrative examples of how Medicare payment components would be applied to CGT admissions.
- Clarify how pediatric gene therapies that lack an NTAP benchmark will be reimbursed, specify a workable crosswalk between Medicaid APR-DRG assignments and the applicable Medicare MS-DRG, and confirm how the payment limits interact with CMMI's CGT Access Model.

State Directed Payments in Medicaid Managed Care (§ 438.6)

CMS proposes the rule to implement Section 71116 of the Working Families Tax Cut legislation (Pub. L. 119-21), together with the related Presidential Memorandum, replacing the current average commercial rate (ACR) ceiling with a new limit tied to the total Medicare payment rate. For rating periods beginning on or after July 4, 2025, SDPs for the “Four Services” that include inpatient hospital, outpatient hospital, nursing facility, and qualified practitioner services at academic medical centers (AMCs) are capped at 100% of the total published Medicare payment rate in expansion states and 110% in non-expansion states, defaulting to the Medicaid State plan rate where no Medicare rate exists. ASTCT recognizes that the use of Medicare rates as the benchmark for these four services follows from the statute. Beginning January 1, 2029, however, the Proposed Rule would extend the same limit to all SDPs (other than grandfathered SDPs) for all provider classes across all 50 states, the District of Columbia, and the U.S. territories.

ASTCT Requests Clarification about the Application of the Rule Given the CMMI CGT Model

ASTCT requests that CMS clarify how the proposed payment limits interact with state participation in the CMMI Cell and Gene Therapy Access Model. While ASTCT presumes the model would not be compromised by the new proposals, the lack of mention in the rule or discussion of how the new payment limits may apply to payments made in connection with a State's participation makes it unclear whether SDPs or targeted FFS payments used to support the treatment centers and the wrap-around services associated with a therapy delivered under the model would themselves be subject to the Medicare-based limits, and whether the model's negotiated, outcomes-based payment arrangements can be reconciled with a limit applied on a per-service basis at each provider. ASTCT therefore requests that CMS confirm in the Final Rule how the Medicare-based SDP payment limits apply to payments made in connection with a State's participation in the CGT Access Model and, to the extent the two frameworks would otherwise conflict, reconcile them so that the limits do not undermine the model's access objectives.

Medicare-based SDP Payment Limits May Decrease Reimbursement for CGT Providers

CGTs, including CAR-T therapies, are a very small class of therapies representing scientific breakthroughs in treating rare and frequently deadly illnesses.¹ These therapies are delivered at specialized programs, which are often located within AMCs, children's hospitals, National Cancer Institute-designated cancer centers, and other highly specialized health systems, after careful vetting and training by the product manufacturers. These providers are among the primary recipients of Medicaid SDPs, which states have historically used to supplement Medicaid managed care reimbursement and support providers serving a high volume of Medicaid beneficiaries. ASTCT recognizes CMS's objective of increasing consistency and

¹ U.S. Food and Drug Administration, Approved Cellular and Gene Therapy Products. Accessed July 12, 2026.
<https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products>

transparency by aligning SDP payment limits with the total published Medicare payment rate methodologies. However, the application of this methodology to CGTs warrants additional consideration given the unique reimbursement structures and specialized delivery systems that support these therapies across state Medicaid programs.

Reimbursement for CGTs varies considerably depending on whether a state reimburses the therapy through the Medicaid pharmacy benefit or includes the therapy within bundled inpatient or outpatient hospital payment methodologies. In states that carve high-cost CGTs out of managed care, reimbursement for the therapy is paid separately through the Medicaid pharmacy benefit and would not be directly affected by the proposed SDP payment limits. In other states, however, reimbursement for CGTs and the associated inpatient and outpatient services is incorporated into bundled hospital payment methodologies, specifically APR-DRGs, with broad inpatient and outpatient SDPs serving as an important mechanism for states to supplement reimbursement for providers delivering these highly specialized services.

CGT administration requires multidisciplinary clinical teams, specialized cellular therapy programs, intensive monitoring, management of treatment-related toxicities, care coordination, and longitudinal follow-up. These services, which include patient evaluation, intensive monitoring, care coordination, and post-treatment follow-up, are reimbursed through bundled hospital payment methodologies such as APR-DRGs and outlier payments. As a result, Medicaid SDPs have served as an important mechanism for states to supplement Medicaid reimbursement and support providers delivering these highly specialized, resource-intensive services.² As of December 2024, 34 states and Washington, D.C., had implemented ACR-based SDPs to support hospitals and physicians at AMCs³ participating in Medicaid managed care. This widespread adoption demonstrates that states have relied on SDPs as a policy tool to strengthen provider participation, improve patient outcomes,⁴ and support access to specialized care.

If the rule is finalized as is, implementation of the proposed Medicare-based SDP payment limits is likely to reduce states' flexibility to support providers delivering these complex therapies, particularly where supplemental payments have been used to address the unique resource requirements associated with CGT delivery.

² Berenson, J., & Hinton, E. (2024, May 22). *What Recent CMS changes to Medicaid state directed payments mean for the future of Medicaid*. Health Affairs Forefront. <https://www.healthaffairs.org/content/forefront/recent-cms-changes-medicaid-state-directed-payments-mean-future-medicaid>

³ America's Essential Hospitals. (2025, April). *Behind the numbers: How state directed payments support essential hospitals* (Policy Brief). <https://essentialhospitals.org/wp-content/uploads/2025/04/How-State-Directed-Payments-Support-Essential-Hospitals.pdf>

⁴ Yates M, Gonzalez-Smith J, Li K, Wang A, Saunders RR. *Value-Based State-Directed Payments in Medicaid Managed Care*. JAMA Health Forum. 2025;6(6):e251666. doi:10.1001/jamahealthforum.2025.1666

Recommendation to Preserve State Flexibility by Allowing SDP Payment Limit Exceptions or Alternative Payment Limit Approaches

By limiting states' ability to provide SDPs, the Proposed Rule may reduce states' flexibility to support providers delivering highly specialized, resource-intensive CGTs. This concern is particularly significant for therapies that disproportionately serve Medicaid beneficiaries. For example, between 50% and 60% of people living with sickle cell disease (SCD) are enrolled in Medicaid,⁵ making Medicaid the primary payer for many beneficiaries who may become eligible for emerging gene therapies. CMS has played a central role in advancing access to these therapies through the creation and implementation of the CMS Innovation (CMMI) Center's CGT Access Model, with participating states representing approximately 84% of Medicaid beneficiaries living with SCD.⁶ Preserving states' flexibility to support these providers through SDPs will help ensure that CGT providers can sustain the specialized workforce, clinical infrastructure, and multidisciplinary programs necessary to deliver current and future CGTs to Medicaid beneficiaries.

ASTCT also notes that the Proposed Rule's allowance for services lacking a published Medicare rate (i.e., a default to the Medicaid State plan approved rate) does not resolve these concerns. State plan rates for the hospital services associated with CGT delivery are frequently well below the cost of care and SDPs currently permit payment above that base rate. Anchoring the payment ceiling to the State plan rate therefore compounds, rather than cures, the underpayment, which is why an exceptions pathway or alternative payment limit methodology (discussed further in the next section) is necessary. The Proposed Rule treats this same circumstance more favorably on the FFS side, where a payment lacking a reasonable Medicare equivalent is excepted from the limit and assessed for efficiency and economy under Section 1902(a)(30)(A) of the Act rather than capped at the base rate. ASTCT recommends that CMS provide comparable flexibility under the managed care payment limit.

ASTCT therefore recommends CMS preserve state flexibility by allowing SDP payment limit exceptions or alternative payment limit approaches for hospitals where Medicare rates are unavailable or do not reflect provider costs for delivering CGTs. This would help preserve Medicaid beneficiaries' access to these therapies.

⁵ Centers for Medicare & Medicaid Services. (n.d.). *CGT Access Model frequently asked questions*. U.S. Department of Health and Human Services. Retrieved July 8, 2026, from <https://www.cms.gov/priorities/innovation/cgt-access-model-frequently-asked-questions>

⁶ Centers for Medicare & Medicaid Services. (2025, July 15). *Innovation insight: CMS model delivers access to sickle cell gene therapy with expansive list of state participants*. U.S. Department of Health and Human Services. <https://www.cms.gov/innovation-insight-cms-model-delivers-access-sickle-cell-gene-therapy-expansive-list-state>

Recommendation to Utilize Aggregate FFS Upper Payment Limit Methodologies When Measuring Compliance with the SDP Payment Limit

ASTCT further recommends that CMS measure compliance with the payment limit in the aggregate rather than on a per-service or per-discharge basis. Medicaid has long applied Medicare-based payment limits in the aggregate under the FFS upper payment limit (UPL) regulations at 42 CFR §§ 447.272 and 447.321. Under those rules, total Medicaid FFS payments to a class of providers (e.g., privately owned hospitals or government-owned hospitals) may not exceed a reasonable estimate of what Medicare would have paid for the same services. States demonstrate compliance annually at the class level using accepted estimation methodologies, and no individual claim is repriced against a Medicare rate. This aggregate structure is what creates room for supplemental payments in FFS Medicaid, where a state may pay above the Medicare-equivalent amount for some services and below it for others, provided total payments to the class remain within the limit.

The Proposed Rule takes the opposite approach. Each individual encounter must independently remain within 100 percent (in expansion states) or 110 percent (in non-expansion states) of the applicable Medicare rate. Applied to CAR-T, every admission must satisfy the limit on its own, with no ability to average across services and no recognition that a transplant center's overall Medicaid payment may remain reasonable even where a particular CAR-T admission is reimbursed below cost. ASTCT urges CMS to apply the aggregate principles that already govern the FFS UPL when measuring compliance with the SDP payment limit. Measuring compliance across a class of services rather than encounter by encounter would allow states and plans to direct payment efficiently within the benchmark. It would also avoid the administrative burden, discussed further below, of repricing individual Medicaid managed care claims through a Medicare Pricer. ASTCT recognizes that, in the FFS provisions of the Proposed Rule, CMS declined to adopt an aggregate approach in part out of concern for the burden of developing new UPL demonstrations for services not currently subject to such limits. That concern does not arise here: the hospital inpatient and outpatient services through which CGTs are delivered already operate under established UPL methodologies, so measuring compliance in the aggregate would rely on a framework states already administer rather than creating a new one.

Recommendation to Preserve State Flexibility to Define Provider Classes

CMS seeks comment on whether and not to define “provider class” in future rulemaking. CMS also proposes an option to define provider classes by reference to Medicaid State Plan provider groupings while establishing Medicare-based SDP payment limits. ASTCT supports CMS's efforts to improve transparency, consistency, and program integrity in the design and oversight of SDPs. However, as CMS considers additional restrictions on how states define provider classes, we urge CMS to preserve states' existing flexibility to define provider classes for SDP purposes.

Under 42 CFR § 438.6(c), a state identifies the class of providers to which a directed payment applies and must apply the payment equally, using the same terms of performance, across all providers within that class. States use this authority to construct classes that reflect their delivery systems and policy goals, such as all inpatient hospitals statewide, AMCs, or children's hospitals. The class definition is therefore the mechanism through which a state can direct enhanced payment to the specialized institutions that deliver CGTs while satisfying the uniformity requirement.

As mentioned previously, CGTs are not commonly provided in standard inpatient programs and are concentrated among a relatively small number of accredited and specialized providers that differ substantially from the broader hospital provider community in terms of their ability to manage complex patients, staffing requirements, and clinical infrastructure. States therefore need flexibility to define provider classes that appropriately recognize these unique delivery models when designing SDPs.

ASTCT recommends that CMS instead maintain the current framework and decline to impose either a narrower federal definition or a broad, uniform category encompassing all hospitals or all outpatient services. A mandated broad class would require states to spread directed payments uniformly across providers that do not deliver these therapies, diluting support for the small number of centers that do. A narrower federal definition would substitute a uniform national rule for state judgments about their own delivery systems. Constraining this flexibility in either direction would limit states' ability to sustain targeted support for the resource-intensive programs on which Medicaid beneficiaries' access to these therapies depends.

While ATSCCT supports CMS's efforts to prevent inappropriate use of provider classes, overly prescriptive federal definitions could unintentionally limit states' ability to direct critical SDPs to CGT providers responsible for delivering these therapies. States are often best positioned to identify provider groupings that reflect local delivery systems, referral patterns, and Medicaid beneficiary needs. Restricting this flexibility could reduce states' ability to support specialized centers that care for a disproportionate share of medically complex Medicaid beneficiaries.

Medicare-based SDP Payment Limits May Disrupt and Limit Patient Access to CGTs

The implications of the Proposed Rule also extend beyond provider reimbursement. Access to CAR-T therapy, as an example of a CGT, is already concentrated within a relatively small number of specialized centers and many Medicaid beneficiaries must travel significant distances to receive treatment. As a result, the Proposed Rule may inadvertently constrain provider participation, resulting in delayed treatment initiation and worsening access to innovative therapies for Medicaid beneficiaries.

Further, freestanding children's hospitals, Medicaid safety-net providers, and hospitals that serve a disproportionate share of Medicaid patients will be particularly affected by this Proposed Rule, because they rely heavily on Medicaid reimbursement to sustain specialized

pediatric and complex care programs. Medicaid covers more than half (53.2%) of hospitalizations among children with multiple complex chronic conditions and more than half (53.8%) of hospitalizations among children living in rural areas,⁷ highlighting the critical role these providers play in ensuring access to advanced therapies for vulnerable populations.

In many communities, these institutions serve as the primary source of specialized care while also functioning as major regional employers and essential components of the healthcare safety net. Maintaining state flexibility to support these CGT providers through SDPs remains an important tool for preserving access to life-saving therapies.

CAR-T therapies are administered for patients with aggressive or relapsed blood cancers. For these patients and others, Medicaid plays a critical role in the cancer care continuum by providing coverage for preventive services, early diagnosis, treatment, and survivorship care. Approximately one in ten adults with a history of cancer rely on Medicaid for health insurance⁸, and one in three children newly diagnosed with cancer are enrolled in Medicaid or the Children's Health Insurance Program (CHIP).⁹ For many of these beneficiaries, access to CAR-T therapy depends on a limited network of highly specialized centers.

Unlike many inpatient oncology services, CAR-T therapies are administered almost exclusively at cell therapy programs, many of them within FACT-accredited cell-therapy transplant programs located within academic medical centers and specialized hematology-oncology centers. This care is exceptionally resource-intensive, often requiring two to three weeks of inpatient care following infusion, transplant-trained nursing staff, intensive monitoring for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS), and complex discharge planning. Similarly, stem cell-based gene therapies frequently require inpatient stays exceeding 30 days to accommodate conditioning chemotherapy, infusion, engraftment monitoring, and multidisciplinary follow-up. Considering these specialized programs are eligible recipients of broad hospital inpatient and outpatient SDPs, we anticipate, at a minimum, reductions in supplemental payments may disproportionately affect the providers responsible for delivering these therapies. Another real potential outcome is that programs are unable to financially sustain themselves and close, putting even more pressure on the limited number of hospitals that are able to cross-subsidize administration of these therapies in some manner.

⁷ Bonavitacola, J. (2025, November 17). *Medicaid pays for half of all pediatric hospitalizations*. The American Journal of Managed Care. <https://www.ajmc.com/view/medicaid-pays-for-half-of-all-pediatric-hospitalizations>

⁸ 2023 National Health Interview Survey data. Analysis performed by American Cancer Society Health Research Services, December 2024. Retrieved on July 6, 2026 from <https://www.fightcancer.org/policy-resources/threats-medicare-funding-changes-provider-taxes-state-directed-payments>

⁹ Ji, X., Hu, X., Castellino, S. M., Mertens, A. C., Yabroff, K. R., & Han, X. (2022). *Narrowing insurance disparities among children and adolescents with cancer following the Affordable Care Act*. JNCI Cancer Spectrum, 6(1), pkab099. <https://doi.org/10.1093/jncics/pkab099>

Recommendation to Evaluate the Impact of Medicare-based SDP Payment Limits on Medicaid Beneficiary Access to CGTs

ASTCT and its members are also concerned that impacts of the SDP payment limits will also extend to Medicaid managed care network adequacy. As outlined in 42 CFR §438.206, states must ensure that Medicaid managed care organizations maintain provider networks that provide reasonable geographic access and sufficient availability of specialized services. If SDP payment limits reduce states' ability to support specialized treatment centers, providers may face greater financial pressure to limit Medicaid participation, reduce specialized service capacity, or delay – even potentially cancel - investments needed to sustain or expand cell and gene therapy programs. Given the limited number of qualified treatment centers nationwide, even modest reductions in provider participation could increase travel burdens, delay treatment initiation, and exacerbate geographic disparities in access for Medicaid beneficiaries requiring lifesaving CGTs.

Given these concerns, ASTCT therefore recommends CMS evaluate the potential impact of the proposed Medicare-based SDP payment limits on beneficiary access to CGTs before finalizing the policy. This analysis should include the effects on network adequacy, provider participation, treatment center capacity, and geographic access among Medicaid beneficiaries receiving care at specialized transplant and cellular therapy programs.

Parallel Concerns Apply to the Targeted FFS Practitioner Payment Limit (§ 447.381)

The Proposed Rule also establishes, at §447.381, a practitioner- and provider-specific limit on targeted Medicaid FFS payments, set at the same 100 percent (in expansion states) or 110 percent (in non-expansion states) of the total published Medicare payment rate. By its terms, this limit reaches AMCs and the physicians and other practitioners who furnish care within them, including the practitioner services associated with delivering CGTs. The concerns ASTCT raises above regarding the adequacy of a Medicare benchmark for CGT-related care therefore apply to the FFS limit as well.

Section 447.381(d) already provides two exceptions to this limit, and their scope matters for CGT-related care. Under the first, where there is no reasonably comparable Medicare rate, the limit does not apply, and the State instead demonstrates that the payment is consistent with the efficiency and economy standard of Section 1902(a)(30)(A) of the Act. Under the second, payments reconciled to a provider's actual, incurred costs are excepted. As written, however, neither exception addresses the circumstance CGT providers face. CMS describes the first exception as directed at broad service categories that Medicare does not cover, such as personal care services, whereas CGT-related services are Medicare-covered. The problem is not that a Medicare rate is absent but that the rate that exists is unrepresentative of, or inadequate for, the Medicaid population receiving these therapies.

That mismatch is stark for SCD gene therapies. Medicare does establish a rate for them, through an MS-DRG together with a New Technology Add-on Payment (NTAP), but the base MS-DRG rate is a small fraction of the therapies' acquisition cost, and the add-on that closes much of that gap is a temporary payment scheduled to expire in FY 2028, per the 2027 Inpatient Prospective Payment System (IPPS) Proposed Rule.¹⁰ The rate also reflects the small Medicare population treated for SCD rather than the Medicaid population that predominantly receives these therapies. ASTCT recommends that CMS broaden the first exception or confirm that it applies where a Medicare rate exists but is not a representative or adequate benchmark for the Medicaid services at issue, including pediatric CGTs.

CMS declined to propose an alternative benchmark for situations in which no reasonable Medicare equivalent exists and invited comment on potential approaches. ASTCT supports the flexible Section 1902(a)(30)(A) demonstration CMS has proposed, which assesses efficiency and economy without imposing a new upper payment limit demonstration, and encourages CMS to preserve that flexibility wherever a representative Medicare rate is unavailable. CMS also considered, though did not propose, permitting targeted payments up to 200% of the State plan base payment in these circumstances. ASTCT reads that alternative as a recognition by CMS that the State plan base payment can itself be insufficient to support the cost of care. ASTCT does not endorse 200%, or any other multiplier, as adequate; a fixed factor may fall well below the actual cost of furnishing CGT-related care. ASTCT recommends instead that CMS either analyze and establish an appropriate adjustment, publishing the supporting methodology for notice and comment before adoption, or apply the exceptions and alternative payment methodologies ASTCT recommends above.

The cost-reconciliation exception in §447.381(d)(2) is appropriate and consistent with ASTCT's recommendation that CMS finalize a cost-based treatment for cost-exempt providers. That exception reaches only providers actually paid on a reconciled-cost basis, however, and does not assist the many providers that furnish CGT-related care under prospective, DRG-based methodologies. ASTCT also notes that CMS declined to adopt an aggregate approach in these FFS provisions, citing the burden of developing new demonstrations and the absence of a reasonable Medicare equivalent for many services. As discussed above, that burden concern does not extend to the hospital services through which CGTs are delivered, which already operate under established aggregate upper payment limit methodologies. Finally, these FFS provisions treat the absence of a Medicare rate more flexibly than the managed care provisions: where no reasonable Medicare equivalent exists, the FFS limit yields to a Section 1902(a)(30)(A) demonstration, while the managed care limit defaults to the State plan approved rate with no comparable efficiency demonstration or cost-reconciliation exception.

¹⁰ Centers for Medicare & Medicaid Services. (2026, April 14). *Medicare program; Hospital inpatient prospective payment systems for acute care hospitals (IPPS) and the long-term care hospital prospective payment system and policy changes and fiscal year (FY) 2027 rates; Requirements for quality programs; and other policy changes* (CMS-1849-P). *Federal Register*, 91(71), 19312–19887. <https://www.federalregister.gov/documents/2026/04/14/2026-07203/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-ipps-and>

ASTCT recommends that CMS extend comparable flexibility to the managed care payment limit, reinforcing the exceptions and alternative methodologies ASTCT recommends above to preserve state flexibility.

Comment Solicitation on the Definition of the Total Published Medicare Payment Rate

Definition of Total Published Medicare Payment Rate Creates Uncertainty for CGTs

CMS is seeking comment on how to define the total published Medicare payment rate, including whether to exclude cost-based methodologies. The proposed rule establishes the "total published Medicare payment rate" as the basis for determining SDP payment limits but does not clearly define which Medicare payment elements are incorporated into that calculation for high-cost CGTs. Should CMS finalize the Proposed Rule as is, this ambiguity is particularly significant for CGTs where Medicare reimbursement frequently consists of multiple payment components rather than a single published payment rate.

The definition also determines how the payment limit applies to providers that Medicare reimburses on a cost basis, which include critical access hospitals, PPS-exempt cancer hospitals, and freestanding children's hospitals. For those providers, CMS proposed to treat their cost-based reimbursement as the total published Medicare payment rate, so that the payment limit would track the cost of care. CMS separately considered, but declined to propose, two alternatives, explaining that it rejected both because the resulting Medicare or State plan rate could fall significantly below what these providers would receive under a cost-based methodology.

For hospitals that provide CGTs, ASTCT supports the approach CMS proposed, which makes the total published Medicare payment rate equivalent to a hospital's cost-based payment, based on the most recent Medicare cost report. To the extent CMS applies any payment limit to these providers, a cost basis is the only defensible benchmark, and it must remain subject to the exceptions and alternative payment methodologies ASTCT urges above to preserve state flexibility. On that understanding, ASTCT recommends that CMS finalize the cost-based approach and issue the implementing guidance the agency has acknowledged is necessary, confirming that the cost-based rate reflects the cost of serving the Medicaid population, rather than the small percentage of the Medicare-enrollee population that may need this type of care.

Neither of the alternatives CMS proposed would support the costs of providing CGTs to Medicaid beneficiaries and we agree that CMS should not move forward with either of them. Under the first alternative, CMS considered excluding cost-based Medicare reimbursement methodologies because provider-specific cost-based payment amounts are not publicly available and may not meet the definition of a total published Medicare payment rate. For providers Medicare reimburses on a cost basis (e.g., critical access hospitals, prospective payment system (PPS)-exempt cancer hospitals, and freestanding children's hospitals), the Proposed Rule would default the SDP payment limit to the Medicaid State Plan approved rate.

These cost-exempt providers deliver a substantial share of CGTs, particularly pediatric gene therapies, and State plan rates for the hospital services associated with CGT delivery are frequently well below the cost of care. SDPs exist precisely to permit payment above the base rate. Anchoring the payment ceiling to the State plan rate would therefore eliminate the additional payments that SDPs provide and compound the underlying underpayment described in ASTCT's recommendation above to preserve state flexibility.

Under the second alternative, states would be required to use only total published Medicare payment rates that undergo the rule making process, such as the Medicare IPPS or Medicare Physician Fee Schedule (PFS) rate, as the basis for the payment limit for all providers, including an "equivalent" published rate for providers Medicare pays on a cost basis. For a freestanding children's hospital or PPS-exempt cancer hospital, that equivalent is an artificial construct. Medicare exempted these providers from prospective payment because IPPS relative weights, calibrated to the diagnoses, acuity, and resource use of Medicare beneficiaries, do not reflect their patient populations, a mismatch that is most acute for pediatric CGTs, for which there is little or no Medicare utilization from which a representative rate could be derived. Requiring states to construct IPPS-equivalent rates for these providers would impose significant administrative burden while producing a benchmark Medicare itself has determined is inappropriate for these hospitals.

ASTCT agrees with CMS's decision to set aside the alternative proposals and utilize the most recent cost-report as the basis for cost-based reimbursement for qualified providers.

Request Confirmation that NTAP and Applicable Medicare Outlier Payments are Incorporated in the Medicare-Based SDP Payment Calculation

Currently, for eligible Medicare beneficiaries, Medicare payment for inpatient stays with CAR-T treatment includes the base MS-DRG payment, NTAP, outlier payments, and other applicable payment adjustments. NTAP are case-level payment adjustments where designations and maximum add-on amounts are established annually through notice-and-comment IPPS rulemaking. They provide additional reimbursement of up to 65% of the cost of the new technology and up to 75% for gene therapies indicated for SCD that are not yet adequately reflected in existing MS-DRG payment rates. These add-on percentages are established under 42 CFR § 412.88(a)(2)(ii), with the enhanced 75% level for the SCD gene therapies set at § 412.88(a)(2)(ii)(C). This distinction is particularly important because CMS has itself recognized that existing Medicare inpatient payment methodologies may not fully account for the costs of these therapies.

In the Proposed Rule, it is unclear whether NTAP and outlier payments would be considered part of the "total published Medicare payment rate" used to establish the proposed Medicaid SDP payment ceiling. If NTAP or outlier payments are excluded from the SDP payment cap calculation, the effective Medicare benchmark for eligible CAR-T admissions could be limited to the base MS-DRG payment, resulting in a payment ceiling that is lower than the total

reimbursement Medicare itself provides for these cases. Consequently, states, providers, and manufacturers are unable to fully evaluate how the proposed payment limits would affect reimbursement for CAR-T therapies or other innovative CGTs.

For example, the 2027 IPPS Proposed Rule details that for CAR-T admissions grouped to MS-DRG 018, the base payment rate for FY 2027 is approximately \$335,904, while Medicare's own measured average cost for these cases is approximately \$412,218. Additional data analysis reveals that roughly two-thirds of MS-DRG 018 cases require outlier payments and these cases all sustain losses, as outlier payments reimburse only a portion of the costs above a fixed-loss threshold. For the hematopoietic stem cell gene therapies used to treat sickle cell disease, which group to MS-DRGs 016 and 017, the base payment rate is approximately \$39,000 to \$43,000, against product acquisition costs of roughly \$2.2 million to \$3.1 million per patient. The associated NTAP, set at the enhanced 75% level, and which still results in a significant shortfall in total payment, is scheduled to expire in FY 2028. A payment ceiling anchored to the base MS-DRG alone would therefore sit far below both the cost of furnishing these therapies and the total amount Medicare itself pays.

ASTCT requests CMS confirm that NTAP and outlier payments are incorporated into the calculation of the "total published Medicare payment rate" for purposes of establishing Medicaid SDP payment limits. The Proposed Rule's reference to hospital-specific payment adjustments does not resolve the treatment of program-wide, case-level adjustments such as NTAP and outlier payments, and explicit confirmation is needed for states, providers, and manufacturers to evaluate how the payment limit would apply to CGT admissions. If NTAP or outlier payments are excluded, CMS should evaluate whether the resulting benchmark appropriately reflects Medicare reimbursement for high-cost, resource-intensive therapies. ASTCT also encourages CMS to provide illustrative payment examples demonstrating how the proposed methodology would be applied to inpatient CGT-related admissions.

Furthermore, the Medicare benchmark is not representative for therapies whose patients fall largely outside the Medicare population. For gene therapies used almost exclusively in children, the Medicare population is not the clinical constituency, so manufacturers may not pursue NTAP designation and there may be little Medicare payment experience reflecting the cost of care. This situation will worsen in FY 2029, when Medicare intends to use median Medicare Advantage payment contracts to set FFS rates – when implemented, a small number of commercial Medicare Advantage plans will then be driving reimbursement for both Medicare FFS and, through this rule, state Medicaid programs. This should not be allowed and underscores why the exceptions and alternative payment limit methodologies described above to preserve state flexibility remain necessary for children's hospitals and pediatric treatment centers, even if CMS confirms that NTAP is included in the payment limit calculation.

Conclusion

ASTCT appreciates the opportunity to provide comments on the Proposed Rule and thanks CMS for its ongoing engagement on the payment and access issues that affect cell and gene therapies and the patients who depend on them. The issues raised in this letter reflect ASTCT's sustained commitment to ensuring that Medicaid payment policy keeps pace with the rapid evolution of these therapies and that the specialized centers delivering them to Medicaid beneficiaries can continue to do so on a financially sustainable basis. ASTCT welcomes the opportunity to discuss any of the issues raised in this letter in greater detail and would be pleased to engage on any technical questions the agency may have. Please contact Molly Ford, ASTCT's Director of Government Relations, at mford@astct.org, with any questions or to arrange a meeting.