ASTCT®
American Society for
Transplantation and Cellular Therapy

June 5, 2026

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

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's comments in relation to the FY 2027 IPPS proposed rule continue to reflect our focus on making innovative therapies available to all Medicare beneficiaries in need of them. To that end, our comments provide feedback to CMS on the MS-DRGs associated with cell and gene therapies, along with the broader issues of rate-setting methodology and overhead cost allocation.

ASTCT thanks CMS for the opportunity to provide comments on the FY 2027 IPPS proposed rule. We are ready to discuss any aspect of our comments further with your staff.

Regards,

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

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

American Society for Transplantation and Cellular Therapy

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Executive Summary

ASTCT appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding the FY 2027 Inpatient Prospective Payment System (IPPS) proposed rule. The following is a summary of our requests in this letter.

1. **MS-DRGs 014, 016 and 017: Stem Cell Transplant and Hematopoietic Stem Cell (HSC) Gene Therapies**
   - ASTCT appreciates CMS' continued guidance to providers clarifying that revenue code 0815 charges are excluded from rate-setting. This is consistent with the statute requiring that donor search and cell acquisition costs be reimbursed through CMS' reasonable cost methodology in the cost report.
   - ASTCT requests that CMS allow an exception to the agency's existing data thresholds specifically for rare disease clinical cases that do not generate sufficient claims data. We also ask CMS to provide options for stakeholders and members of the public to consider, which would lead to more useful and specific feedback on potential options.
   - ASTCT implores CMS to begin active work on potential solutions well ahead of the FY 2028 rule-making cycle and to use the viable ideas that stakeholders have provided to the agency in the past. We also ask CMS to generate additional suggestions by collaborating with stakeholders such as ASTCT, such as through Town Halls or other events that facilitate stakeholder input, as ASTCT and others have requested previously.
   - Finally, ASTCT asks that CMS work to implement solutions to the issues associated with cell and gene therapy payment before the planned conversion to a different rate-setting methodology, to ensure that patient access is not affected in the interim.

2. **MS-DRG 018: Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies**
   - ASTCT supports the proposal to continue the modified payment and rate-setting methodology for MS-DRG 018, including the use of an adjustor for applicable clinical trial, expanded access, and other cases with no product cost.
   - ASTCT requests that CMS consider ways to improve the base payment for MS-DRG 018 as part of its analysis of stakeholder feedback related to future payment for cell and gene therapies, and identify which potential solutions are of most interest to the agency so interested parties can assist the agency with analysis.
   - ASTCT urges CMS to examine splitting out cellular therapies from the Drugs and Cellular Therapies cost center, as the agency recognizes the differences between regular drugs and autologous cellular therapies in many of its own policies and proposals.

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3. Clarification and Codification of Cost Allocation Principles

- ASTCT requests that CMS correct its statement that "*[t]he purchase price includes costs for the complete process of extracting and preparing the biological for infusion,*"as it is inaccurate and does not reflect the experience of most hospitals providing autologous therapies.
- ASTCT requests that, if the current proposal is finalized, CMS clarify that it only applies to cost reporting periods beginning on or after October 1, 2026, and that prior periods are not subject to audit or adjustment.
- ASTCT requests that CMS develop a prospective framework that advances cost-reporting accuracy while preserving appropriate recognition of the true overhead burden these programs represent. We welcome the opportunity to work with the agency to develop such a framework.

4. New Technology Add-on Payment (NTAP) Methodology

- ASTCT asks that CMS consider an additional pathway of an extended NTAP availability window for autologous cell and gene therapies, or consider other options to bolster claims data used in setting the post-NTAP MS-DRG adjustment.

5. FY 2029 Rate-Setting Methodology

- ASTCT strongly urges CMS to repeal the market-based MS-DRG methodology, due to CMS' own comments in CY 2026 OPPS final rule that *"the vast majority of stakeholders were opposed to the proposals."*[1]
- ASTCT is concerned that the FY 2027 IPPS proposed rule contains no discussion of the market-based MS-DRG relative weight methodology that was finalized in the CY 2026 OPPS final rule. ASTCT requests that CMS include a full summary of the final decision from the CY 2026 OPPS final rule, including commenter concerns, along with any substantive updates since the publication of that rule.
- ASTCT requests that CMS consider alternatives to the market-based rate-setting methodology suggested by stakeholders, including a study of the claims that hospitals submit to their Medicare Administrative Contractors (MACs) for beneficiaries receiving care through Medicare Advantage (MA) plans – otherwise known as 'shadow claims'.

[1] CY 2026 OPPS Final Rule, FR 54020. Published November 25, 2025.

MS-DRGs 014, 016 and 017: Stem Cell Transplant and hematopoietic stem cell (HSC) Gene Therapies

MS-DRG 014: Allogeneic Bone Marrow (Stem Cell) Transplantation

ASTCT appreciates that CMS continues to provide guidance to providers, through both transmittals and regulatory text, clarifying that revenue code 0815 charges are excluded from rate-setting. This guidance is consistent with the statute, which requires that donor search and cell acquisition costs be reimbursed through CMS' reasonable cost methodology in the cost report.

MS-DRGs 016/017 are not a Long-Term Solution for HSC Gene Therapies

As ASTCT noted in its FY 2025 and FY 2026 comment letters, the assignment of HSC gene therapies to MS-DRGs 016 and 017 was an appropriate interim step, since the patient's care episode is, roughly, clinically homogeneous to other autologous stem cell transplants. Hence, these MS-DRGs were the closest fit and an appropriate mapping option at the time of launch.

However, these mappings were made before product costs were known. Given that product acquisition costs now range from $2.2M to $4.25M per patient for the FDA-approved gene-modified autologous grafts that are being used for genetic correction, CMS' resource-homogeneity principle is now being violated to a fairly massive degree. This difference in typical resource utilization of unmodified autologous transplants (which have FY 2026 base MS-DRG payment rates of $39,000 to $43,000) and gene-modified grafts is so dramatic that MS-DRGs 016/017 is not a viable long-term solution for these multi-million-dollar therapies.

Additionally, rate-setting data will be distorted in one of two ways if these gene therapy cases remain in MS-DRGs 016 and 017. First, the high product acquisition costs of gene therapy cases will inflate the relative weight and produce a rate that overpays for traditional autologous transplant cases and still underpays for gene therapy cases. Or, second, those high-cost cases will be trimmed from the rate-setting data entirely and, thus, contribute nothing to the relative weight calculation and perpetuate the cycle of inadequate base payment.

Allowing NTAP to Expire in FY 2028 Without a Solution Is Inconsistent with CMS' Stated Priorities

CMS has publicly recognized treatment for sickle cell disease (SCD) as a priority, as reflected by the agency's creation of the CMMI Cell and Gene Therapy Model and its issuance of NTAP at the 75% level for the gene therapies indicated for SCD rather than the usual amount. ASTCT applauds CMS for these efforts and asks the agency to continue its focus on providing innovative therapies to beneficiaries with this devastating illness.

As ASTCT noted in our FY 2025 and FY 2026 comment letters, even with the current 75% NTAP in place, hospitals are experiencing significant losses when providing these therapies. CMS proposes to extend NTAP for FY 2027, and ASTCT supports this proposal. Without NTAP, the losses will become even more devastating, given the tremendous portion of the case cost that will be paid through the outlier formula. The outlier formula, by design, requires hospitals to absorb a loss before any additional payment begins; even then, hospitals are only able to recover 80 cents on the dollar above the fixed-loss threshold. The use of a multi-million-dollar therapy that results in hundreds of thousands of dollars of loss cannot be averaged-out by other Medicare cases, nor can the loss be made up via margins on non-Medicare cases. From start to finish, the process of providing an autologous gene therapy to a patient with SCD stretches for most of a year. Patients with SCD typically require multiple collection cycles, separated by at least two weeks, to achieve the necessary cell yield. Cell collection is followed by product manufacturing and administration of the therapy, which requires a hospital stay of several weeks.

Because of this extensive timeline, it is unlikely that CMS saw any cases in the IPPS data during the first year of NTAP eligibility (FY 2025). Given the unique focus CMS has placed on beneficiary access to these therapies, ASTCT recommends that the agency utilize its equitable adjustment authority to allow for a delayed start to the NTAP start period so that more claims can accumulate in order to inform future rate-setting as CMS considers next steps. In the proposed rule, CMS indicated that it is waiting for additional claims to be submitted before changing how the agency considers cell and gene therapies. ASTCT requests that CMS review and share volume and charges from the most recent year of data, as it is not yet available in MedPAR but will be critical in thinking about solutions and potential modifications going forward. This information will be important for stakeholders to better understand when considering how we can help CMS consider future options before the MS-DRG modification request deadline in October.

CMS Should Share Potential Options the Agency is Considering for Cell and Gene Therapies

In the FY 2027 proposed rule, CMS shared that the agency:

> *". . . is in the process of carefully considering the feedback we have previously received about ways in which we can continue to appropriately reflect resource utilization associated with cell and gene therapies while maintaining clinical coherence and stability in the relative weights under the IPPS MS-DRGs,"* and that the agency continues to *". . . examine these complex issues in consideration for future rulemaking."*

ASTCT notes that CMS' response—like its responses to analogous mapping requests in prior years—once again reflects the agency's broader, multi-year statement that it is considering stakeholder feedback on cell and gene therapy payment proposals. ASTCT recognizes the complexity of this review and strongly urges CMS to – at a minimum – share the options that are most appealing to the agency, either in the FY 2027 IPPS final rule or in a separate request for information process.

Sharing CMS' perspectives on the ideas submitted thus far will provide stakeholders with the time needed to digest this information and use it to frame comments to CMS - either ahead of the October DRG modification deadline or through comments on future proposed rules. The window for making these changes to support beneficiary access is short; therefore, ASTCT urges CMS not to delay thinking about solutions until after NTAP for the two gene therapies for SCD have expired. Doing so risks creating a gap in providing fair and appropriate payment to hospitals that will impact the beneficiary care options, given that hospitals simply cannot absorb multi-million dollar losses.

ASTCT also urges CMS to resist deferring action on the grounds of insufficient claims volume. As ASTCT stated in our FY 2024 comment letter, CMS' traditional method of waiting for claims data to accumulate will not work if the reimbursement barrier is so high that most hospitals are unwilling to provide these treatments in the first place. Additionally, as CMS is aware, cell or gene therapies for rare diseases will, by their very nature, never generate large volumes of FFS claims. If CMS continues to apply standard claims volume thresholds to therapies that serve small patient populations, the agency will find itself in a position where the data required to act never materialize and beneficiary challenges in accessing these therapies will remain perpetually unaddressed.

ASTCT requests that CMS allow an exception to the agency's existing data thresholds specifically for rare disease clinical cases that do not generate sufficient claims data. We also ask CMS to provide options for stakeholders and members of the public to consider, which would lead to more useful and specific feedback on potential options.

ASTCT implores CMS to begin active work on potential solutions well ahead of the FY 2028 rule-making cycle and to use the viable ideas that stakeholders have provided to the agency in the past. We also ask CMS to generate additional suggestions by collaborating with stakeholders such as ASTCT, such as through Town Halls or other events that facilitate stakeholder input, as ASTCT and others have requested previously.

Finally, ASTCT asks that CMS work to implement solutions to the issues associated with cell and gene therapy payment before the planned conversion to a different rate-setting methodology, to ensure that patient access is not affected in the interim.

MS-DRG 018: CAR-T and other immunotherapies

Cost Allocation Proposal Misconstrues Hospitals' Role in Creating Cellular Therapies

ASTCT has significant concerns with CMS' inclusion and singling out of CAR-T (and potentially other autologous biologics) in the agency's proposals for cost allocation standards. We share these concerns in a later section and request that CMS not finalize this as proposed.

Support for Continuation of MS-DRG 018 Payment and Rate-Setting Methodology

For FY 2027, CMS proposes to continue applying the modified payment and rate-setting methodology for MS-DRG 018, including use of an adjustor of 0.17 for applicable clinical trial, expanded access, and no product-cost cases. This proposal is consistent with the methodology CMS finalized in the FY 2024 IPPS final rule. Specifically, when calculating the average cost for MS-DRG 018 used to determine its relative weight, CMS proposes to continue excluding applicable clinical trial cases (e.g., those with diagnosis code Z00.6 and no condition code –ZC), expanded access cases (e.g., those with condition code 90), and cases with standardized drug charges below the median standardized drug charge of clinical trial cases.

ASTCT strongly supports CMS' proposal to continue these unique payment and rate-setting methodologies for MS-DRG 018. As ASTCT has noted in each of our comment letters from FY 2023 through FY 2026, the exceptional methodology CMS has implemented for this MS-DRG remains both necessary and appropriate. The clinical trial pipeline for CAR-T therapies and the other immunotherapies in this MS-DRG continue to be robust, and the number of cases without product cost (i.e., mainly clinical trial cases) in the MedPAR data remains significant. CMS' approach of setting aside those cases and adjusting the case count accordingly continues to be important to ensure that MS-DRG 018's relative weight is not artificially suppressed and to prevent cases without product cost from being overpaid.

Request for Technical Correction to Cost Reporting Instructions for Line 78

ASTCT recently contacted CMS' Division of Cost Reporting to request clarification regarding what appears to be inconsistent language for CAR-T costs in the Form CMS 2552-10 cost reporting instructions related to Worksheet D, Part V, and Worksheet D-3, line 78. For transparency and consistency, ASTCT is also including the same request here.

Section 4024.5, Worksheet D, Part V, states: *"Line 78 -- For CAR T-cell immunotherapy, enter the charges for services for all patients (for Medicare, these are billed under revenue codes 0871, 0872, 0873, 0874, and 0891)."*

Similarly, Section 4027, Worksheet D-3, instructs hospitals to report charges associated with these same revenue codes on line 78.

These revenue codes correspond to the following CAR-T services:
• Revenue code 0871: Procuring or collecting cells for CAR T
• Revenue codes 0872 and 0873: Processing and storing cells for CAR T
• Revenue code 0874: Administration of CAR T-cell therapy
• Revenue code 0891: CAR T-cell manufactured biologic product

However, the instructions in Section 4013, Worksheet A, line 78, specifically instruct providers to exclude costs associated with the administration procedure. CMS states:

"Line 78 -- Effective for cost reporting periods beginning on or after October 1, 2022, enter the hospital costs for procuring, storing, and processing chimeric antigen receptor T-cells (CAR T-cell) for immunotherapy infusion (FDA-approved CAR T-cell immunotherapies only). This includes the cost of the CAR T-cell manufactured biologic (i.e., the cost paid to the manufacturer). ***Do not include costs for CAR T-cell immunotherapy transplants****..."* [emphasis added]

ASTCT believes the reference to "*CAR T-cell immunotherapy transplants*" was intended to refer to the administration or infusion of the CAR-T product. This interpretation appears to be consistent with the overall structure of the cost center, which otherwise focuses on cell acquisition related activities and mirrors the treatment of cost center 77 for donor search and cell acquisition.

As currently written, the instructions direct hospitals to include charges associated with revenue code 0874 on Worksheet D and Worksheet D-3, and exclude the corresponding administration costs from Worksheet A, line 78. This creates a mismatch between the costs and charges assigned to the CAR-T cost center.

Because the administration or infusion procedure would generally be reported through inpatient routine cost centers or outpatient clinic cost centers, ASTCT respectfully requests clarification regarding whether inclusion of revenue code 0874 in the Worksheet D and Worksheet D-3 instructions was intentional. If not, ASTCT requests that CMS revise the instructions to remove revenue code 0874 from the list of charges reportable on line 78 in order to maintain consistency between the costs and charges assigned to the cost center.

Finally, ASTCT requests clarification regarding whether CMS intends line 78 to apply exclusively to CAR-T therapies or whether other autologous cellular therapies should also be reported in this cost center.

Inadequate Base Payment for MS-DRG 018 Continues to Drive Excessive Outlier Dependence

While ASTCT supports the continued use of the unique MS-DRG 018 rate-setting methodology, we reiterate our concerns regarding the inadequacy of the base payment for MS-DRG 018 and its disproportionate impact on the IPPS outlier pool. ASTCT has raised this concern consistently since our FY 2023 comment letter.

The FY 2025 MedPAR data used for FY 2027 rate-setting show that 65.8% of MS-DRG 018 cases received outlier payments; this is far more than any other MS-DRG in IPPS. And of the cases that received outlier payment, the propotion was substantial – outlier accounted for just under 40% of the total dollars received. ASTCT notes that this is not a one-time data point. As we have articulated in earlier letters, 66% of MS-DRG 018 cases in the FY 2023 MedPAR data received outlier payments.

CMS has stated that outlier dollars are for any type of unusually expensive cases. Nonetheless, ASTCT continues to believe that, when two-thirds of cases in a single MS-DRG require outlier payment to approach the case's calculated cost, it is evidence the outlier policy is not functioning as designed. In fact, it is evidence that the base payment is fundamentally *insufficient*. This view matches CMS' statements in the 2003 discussion of how the outlier methodology was being changed: *[t]he Congress intended that outlier payments would be made only in situations where the cost of care is extraordinarily high* ***in relation to the average cost of treating comparable conditions or illnesses****."*[2] *[emphasis added]*

It does not stand to reason that 66% - i.e. the majority - of cases within MS-DRG 018 are high in relation to the average cost of treating those same patients. Rather, this indicates that the base payment does not take into account the true costs of treating these beneficiaries, so the cases skew towards outliers.

By design, the outlier pool is funded by a reduction to the operating standardized amount applied to all IPPS cases. When a single MS-DRG draws disproportionately from the outlier pool, it places upward pressure on the fixed-loss outlier threshold, which has more than doubled since FY 2017 and is proposed at $51,704 for FY 2027. That rising threshold means that every hospital must absorb a larger mandatory loss before outlier payments begin, across all MS-DRGs. Inadequate payment in MS-DRG 018 is, therefore, not a narrow specialty concern; it is a system-wide cost that is borne by the entire IPPS hospital community. To achieve a base payment that more accurately reflects the true cost of CAR-T and other immunotherapies, we respectfully request that the agency address the core problems in the MS-DRG's current structure.

Charge Compression and Lagging CCRs Continue to Cause Inadequate Base Payments

The most notable problem driving the mismatch between costs and the base payment stems from charge compression—particularly for the cellular therapy product itself. It is true that

[2] Mediare Program; Change in Methodology for Determining Payment for Extraordinarily High-Cost Cases (Cost Outliers) Under IPPS. June 2003. FR 34496.

hospitals have improved their charging practices to follow CMS' guidance in the *Provider Reimbursement Manual.* It is also notable that, in the FY 2021 and FY 2022 IPPS Final Rules, CMS indicated that hospitals are not precluded from setting charges in accordance with their CCRs. Yet, CMS has stopped short of fully clarifying for hospitals *which* CCRs are most appropriate to use for certain items—leaving providers to decide this on their own. In light of the rationale CMS presents for the market-based rate-setting in both the FY 2021 IPPS and the CY 2026 OPPS proposed rules (i.e., overreliance on the chargemaster), providers are likely to have new concerns about the optics of setting setting appropriate charges in relation to their costs.

Hospitals are expressly allowed to set their charges in accordance with their own overall operating and capital CCRs and may also account for pharmacy overhead or handling. But, even when they do so, the resulting charges are unlikely to yield an accurate picture of actual cost, given that CMS applies the national drug CCR when standardizing those charges for rate-setting purposes, rather than an overall national CCR. This differential causes a significant mismatch between costs for purposes of real-time hospital payment compared to the calculated cost used in future rate-setting calculations.

For example, the drug CCR was 0.18 for FY 2025; the average operating and capital CCR of hospitals providing the therapies assigned to MS-DRG was approximately 0.25. The difference of 0.07 (0.25-0.18) undervalues the costs of these therapies by tens of thousands of dollars for each case during rate-setting. The problem is only compounded as product prices rise. Further, the CCR used by CMS to calculate payment is based on the hospital's overall CCR from two fiscal years prior (this has been deemed a "lagging CCR" by HFMA[3]) not the hospital's current CCR, which may be substantially different.

On the other hand, hospitals may also have determined that using the drugs and cellular therapies CCR is the most appropriate reference for use in setting charges. This is a reasonable view, given that CMS renamed the CCR accordingly in FY 2025 and stated that: *"[w]e believe that relative to those 19 cost centers, cellular therapies are most similar to drugs given that hospitals have generally calibrated their CAR T-cell therapy product charges to the "drugs" cost center CCR."*

ASTCT views CMS' statement as affirmation that hospitals that use their departmental drugs and cellular therapies CCR are justified in doing so if it aligns more closely with their costs. If CMS views this differently, however, the agency should provide clarification in the final rule. Clarification is necessary because providers continue to be concerned about charging optics, despite CMS' permission that it is acceptable to set charges in accordance with their CCRs. This

[3] HFMA. July 10, 2020. FY 2021 IPPS Proposed Comment Letter: Part 1 – Median Rate Reporting and Market-Based MS-DRG Rebasing. https://www.hfma.org/guidance/regulatory-and-accounting-resources/comment-letters/fy2021-ipps-proposed-rule-comment-letter-part1-median-rate-reporting-market-based-msdrg-rebasing/

concern has been further exacerbated by CMS' statements in the CY 2026 OPPS final rule about shifting away from reliance on the chargemaster.

CMS' own calculations exemplify how the issue of charge compression creates downward pressure on the base payment rates. In the rule's section about the rate-setting methodology for MS-DRG 018, CMS states:

> *Under our proposal to continue to apply this methodology, with the proposed modification as described, based on the December 2025 update of the FY 2025 MedPAR file used for this proposed rule, we estimate that the average costs of cases assigned to MS-DRG 018 that are identified as clinical trial cases ($71,039) were 17 percent of the average costs of the cases assigned to MS–DRG 018 that are identified as non-clinical trial cases ($412,218). [FY 2026 IPPS PR; FR 19394]*

CMS' calculations show an average case cost of $412,218 but the base proposed payment rate for FY 2027 is $335,904—a difference of almost $80,000. This cost and payment gap is glaring and expected to get worse given that the national drug CCR has dropped further (to 0.171) for FY 2027.

As ASTCT has argued since the first CAR-T approval a decade ago, CAR-T and other autologous immunotherapies are not like other drugs and biologicals. CMS agrees with ASTCT in many of the agency's own policy positions. For example, in this year's IPPS proposed rule, CMS added a new layer of distinction for CAR-T products when it required that hospitals handle them differently for purposes of overhead cost allocation. CMS has described these products as purchased clinical services and stated in the FY 2025 final rule that the agency "*may consider changes to the CCRs used for gene and cellular therapies in future rulemaking.*"

ASTCT urges CMS to explore alternative methodologies for rate-setting that also allow for modifications to charging practices simultaneously, including the HFMA Direct Cost Model, which was proposed in their FY 2021 comment letter and is based on the internationally referenced Australian Patient Costing Standards. A change of this type would allow hospitals to rebase their charges without suffering from decreased payment for several years. Unless the agency does so, hospitals are unlikely to be able to move away from applying appropriate mark-ups, since charges are used in the NTAP and outlier calculations as well as for outpatient rate-setting.

For these reasons, ASTCT asks CMS to pull cell and gene therapies out of the Drugs and Cellular Therapies cost center; revert the name back to "drugs;" and create a dedicated cost center for cell and gene therapy products using data collected through cost report line 78.

Clarification and Codification of Cost Allocation Principles (Section X.D.3)

ASTCT noted CMS' attention to cost allocation methodology on the Medicare cost report and understands the agency's interest in ensuring that Administrative and General (A&G) overhead is allocated accurately and consistently. In the FY 2027 proposed rule, CMS proposes to codify cost allocation principles at 42 CFR 413.24(d)(8) and require providers to exclude purchased services and supplies from the accumulated cost statistic used to allocate A&G overhead costs.

ASTCT understands the general principle CMS is articulating: that including the full purchase price of an externally sourced product or service in the accumulated cost statistic can result in a disproportionate allocation of hospital overhead to that cost center, particularly when the purchase price already incorporates the external entity's own overhead, but we disagree with CMS' characterization of CAR-T and object to CMS' codifying its proposal as written due to a lack of consistency and clarity about the subject matter. For example, the proposed rule uses the terms "*purchased services*," "*purchased clinical services*," and "*purchased products*" interchangeably, yet these terms are not equivalent.

Additionally, CMS is allowing incorrect assumptions about autologous biologics to guide its proposal. We express our concerns in detail in the following sections and request that CMS address all of these before it codifies the proposals.

CMS is Making an Inaccurate Presumption about Hospital Costs for Autologous Biologicals

In the CY 2026 MPFS final rule, CMS finalized a new payment policy despite significant protest from the provider community. As ASTCT has been arguing for years, the clinical services required to make CAR-T and other autologous biologicals are services provided by the hospital to a registered patient of the hospital and, as such, are like other ancillary services the hospital provides. However, CMS finalized the following:

> *Accordingly, we are finalizing that preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy be included in the payment of the product itself, consistent with the existing payment policy for CAR T-cell therapies. [CY 2026 MPFS Final Rule; FR 49544]*

ASTCT continues to object to this policy. We remain puzzled that CMS believes the payment for hospital clinical services are included within the payment for products, given that the majority of hospitals incur the costs of providing these services to their patients. We note that CMS did not clarify that payment by manufacturers was an option prior to the CY 2026 MPFS final rule. Furthermore, per CMS' own claims processing instructions, hospitals have several options for how they report their charges to CMS.

In the FY 2027 IPPS proposed rule, the agency is attempting to further stretch their interpretation of this payment decision across how hospitals allocate overhead to various parts of the CAR-T process. CMS highlights CAR-T and makes the following statements:

> *The amounts paid by the transplant hospitals to OPOs or other transplant hospitals for purchased organs has increased significantly over the years. This increases improper allocation of overhead costs.* ***Another example of this is when hospitals purchase CAR T-cell biologicals. The purchase price includes costs for the complete process of extracting and preparing the biological for infusion****. Including these direct costs in the accumulated cost statistic would improperly and disproportionately allocate overhead to the CAR T-cell cost center without any relationship between the hospital's overhead and the purchased biological. [emphasis added]*

First, CMS' use of "*another example*" is unclear; we do not know if the agency is specifically focusing on CAR-T products or if it is seeking to apply the discussion to a broader category of therapies—i.e., all biologicals, all cell and gene therapies, or just certain specifically identified autologous biologics.

Second, the cost allocation principle that CMS proposes to codify was developed primarily in the context of purchased services that are obtained from external Medicare-paid entities, such as organs purchased from Organ Procurement Organizations (OPOs). In that context, the double allocation concern is straightforward: the external entity is itself a Medicare-paid provider whose costs and overhead are already recognized within the Medicare payment system. ASTCT recognizes CMS' concern that including the full purchase price in the accumulated cost statistic would cause the purchasing hospital to attract an additional layer of A&G overhead on top of costs that have already been fully loaded by the selling entity. However, ASTCT disagrees with CMS that commercially purchased pharmaceutical products fall into this category. In fact, they represent a materially different policy scenario than purchased services that are obtained from external Medicare paid entities.

Third, CMS' phrase that "*the purchase price includes costs for the complete process of extracting and preparing the biological for infusion"* indicates that the agency misunderstands how CAR-T and other autologous biologicals are created.

Lastly, CMS continues to ignore the fact that an estimated 10% of these patients never receive the product due to clinical progression; in these cases, the hospital does not receive any payment for the clinical services it provided because of CMS' inclusion of payment for these services in its payment for the product. When no product is provided, there is no payment – bundled or otherwise – for that clinical care.

The Purchase Price for Autologous Biologics Does Not Include Costs for the Complete Process

In the CY 2026 MPFS final rule, after CMS reiterated that providers will not receive separate payment from CMS for these services, the agency clarified two additional policies. First, that any payment for these services from manufacturers to hospitals should be considered *bona fide* service fees and not price concessions. Second, that hospitals are not required to take payment from manufacturers. CMS stated:

> *This policy addresses only how manufacturer-paid amounts are reflected in ASP;* ***it does not require hospitals or physicians to enter financial arrangements with manufacturers or dictate commercial terms****.* ***By not mandating such arrangements, we provide interested parties flexibility to structure relationships consistent with operational needs and applicable law, supporting site-specific decisions and reducing administrative burden****. Except for the ASP reporting clarification described in this section, this final rule does not change any statutory or regulatory price-reporting definitions or methodologies, including AMP and best price. [CY 2026 MPFS Final Rule p. FR 49546, emphasis added]*

Thus, there are at least three scenarios under which cells are collected for the development of an autologous biologic:

1) A hospital collects a patient's cells and invoices the product's manufacturer per a pre-determined arrangement;
2) A hospital collects a patient's cells and does not invoice a product's manufacturer; or
3) A hospital pays a separate entity to collect the patient's cells on their behalf and does not invoice a product's manufacturer.

Scenario 1 is the only potential scenario that may be in keeping with CMS' perspective – in this case, the hospital would be paid by the manufacturer and then buy the subsequently manufactured product at a cost that theoretically incorporates its full spectrum of costs. Scenarios 2 and 3 have been, to-date, the most common for hospitals providing CAR-T. In these scenarios, the hospital incurs direct costs that that are not compensated by a manufacturer. Further, in scenario 2, the hospital's own staff and resources are used to collect the cells of the hospital's registered patient, just as they would for any other patients that are under the care of their treating physician and whose services are being rendered at their hospital. As such, these services are the same as any other clinical service provided to the hospital's patients, and it is appropriate for them to receive overhead.

CMS' instructions for line 78 in various cost report worksheets clearly support the viewpoint that the hospital is incurring the cost for cell collection and cell processing and must report this data in the cost report. CMS' language reads:

> *"Line 78 -- Effective for cost reporting periods beginning on or after October 1, 2022, enter the* ***hospital costs for procuring, storing, and processing*** *chimeric antigen receptor T-cells (CAR T-cell) for immunotherapy infusion (FDA-approved CAR T-cell immunotherapies only). This includes the cost of the CAR T-cell manufactured biologic (i.e., the cost paid to the manufacturer).*

To follow these instructions, hospitals track the portion of their costs associated with CAR-T-related cell collection and processing activities (e.g., shipping of collected cells, receiving of manufactured cells, ensuring the chain of custody/chain of identity-verification steps) from all patients treated in the relevant cost report year. They then reclassify these costs from the departments in which they were originally recorded. Once reclassified, the normal Medicare cost finding process and overhead allocations occurs on Worksheet B series. As a result, our understanding is that overhead costs are allocated to Line 78 in the same manner as they are allocated to other ancillary departments.

Separate from the product acquisition costs themselves, the other costs attributed to line 78 are hospital operations that consume labor, equipment, space, utilities, information systems, and A&G support. Under traditional Medicare cost-finding principles, there would ordinarily be a basis for assigning an appropriate share of overhead to those activities. That is because a hospital is not simply purchasing and administering a product. Rather, it is actively performing clinical and laboratory services that require staff, equipment, facilities, quality controls, storage systems, and broader institutional support. CMS' proposal is based on an assumption that does not fully account for hospitals that are actually performing collection, storage, and processing in-house.

ASTCT appreciates CMS' apparent concern about the rising costs of autologous biologic products. This concern may have led to the agency's disproportionate focus on these products and the clinical services that are associated with them. ASTCT reiterates our position that hospitals have *no control* over manufacturer prices for these biological products. The complex clinical work associated with the patient care services that hospitals provide should not be ignored or discounted out of price-related concerns.

If CMS is frustrated with the prices of current products and interested in reducing product costs, the agency should work with the FDA to allow for resource-based payment of in-hospital autologous biologic manufacturing. In the meantime, hospital costs for appropriate clinical services should be handled in compliance with standard hospital policies and CMS' cost reporting requirements. In the 2026 OPPS final rule, CMS specifically noted that the agency allows flexibility in hospital decision-making in order to reduce administrative burden. Yet, CMS' current proposal creates a new series of burdensome steps and places specific constraints that preclude the appropriate cost allocation practices for the types of services being delivered.

ASTCT requests that CMS correct its statement that "*[t]he purchase price includes costs for the complete process of extracting and preparing the biological for infusion*." This statement is inaccurate and does not reflect the experience of most hospitals that provide autologous therapies.

Prior Guidance Has Not Been Sufficiently Clear to Support Retroactive Application

ASTCT respectfully disagrees with CMS' characterization that the requirements proposed for codification reflect clearly established instructions that providers have consistently been expected to follow. General cost-finding principles in 42 CFR Part 413 and the *Provider Reimbursement Manual* (PRM-2, Chapter 40, Section 4020 and PRM-1, Chapter 23, Section 2314 A) allow providers to exercise their judgment in determining whether and how to apply allocation statistics. This flexibility includes circumstances that warrant excluding a cost center from overhead allocation entirely.

Accumulated cost has been a recognized and accepted component of A&G allocation methodology for years. This recognition extends to high-cost purchased items and services, such as drugs, biologicals, devices, etc. As such, ASTCT does believes it is inappropriate to characterize this proposal as a *clarification* of pre-existing obligations. It is also inappropriate to single out cellular immunotherapies like CAR-T, since they are purchased products like other high-cost drugs or biologicals. They should not be treated like purchased clinical services, for the reasons outlined above.

If CMS finalizes codifying this proposal despite our objections, the agency should confirm in the final rule that this framework would apply *only* prospectively to cost reporting periods beginning on or after October 1, 2026. Additionally, whatever methodology CMS ultimately adopts should reflect the reality that hospitals operating transplant and cellular therapy programs carry substantial and legitimate overhead costs that exist independently of the acquisition cost of any individual therapy. Cell collection, complex care coordination, compliance, accreditation, and clinical program management are genuine institutional costs. These costs do not diminish simply because a therapy is externally sourced or carries a high purchase price.

ASTCT requests that CMS develop a prospective framework that advances cost reporting accuracy and preserves appropriate recognition of the true overhead burden these programs represent. We welcome the opportunity to work with the agency to develop such a framework.

Newness Dates for NTAP Should Allow for Flexibility Based on Product Type

ASTCT appreciates the changes that CMS has made to NTAP in the past several years. This is particularly important given technology changes, particularly the increase in NTAP maximum amount percentages and the modification of the anniversary date to allow for more therapies to have NTAP for three full fiscal years.

CMS' NTAP section begins with a discussion on newness and states the following:

> *(1) Newness Criterion - Under the first criterion, as reflected in § 412.87(b)(2), a specific medical service or technology will no longer be considered ''new'' for purposes of new medical service or technology add-on payments* ***after CMS has recalibrated the MS–DRGs, based on available data, to reflect the cost of the technology****. [FR 19396; emphasis added]*

As ASTCT has argued in previous comment letters, the unique manufacturing processes associated with autologous cell and gene therapies have clear repercussions on the ability of the MS-DRG base payment to adjust, per CMS' expectations, by the end of the NTAP period. These therapies take significantly longer to move from FDA approval to actual availability and are therefore delayed in producing the data necessary for MS-DRG recalibration. This delay stems from the longer decision-making process and the length of time it takes to move from patient cell collection to treatment; the latter process can take more than six months for autologous cell-based gene therapies. When assuming a three-year NTAP eligibility period and given the two-year time lag in the data that CMS uses for rate-setting, the number of claims that will exist in the data by the second year of NTAP will be very low and it is unlikely that the agency will be able to "*recalibrate the MS-DRGs…to reflect the cost of the technology.*"

ASTCT asks CMS to consider an additional pathway of an extended NTAP availability window for autologous cell and gene therapies or that CMS consider other options to bolster claims data that are used in setting the post-NTAP MS-DRG adjustment. CMS could combine data from all three NTAP data years in the case of low-volume data signals or allow for the use of a "first claim date" to set the start of the NTAP timeframe for these therapies, with the intentional goal of allowing data to accrue for low-volume products. CMS could also examine its projections of NTAP therapy use against claims data to assess whether additional time for data collection under NTAP is needed. For example, CMS listed that it expected exagamglogene autotemcel and lovotibeglogene autotemcel to be used in 117 and 40 cases in FY 2025[4], respectively; ASTCT does not know the actual number but suspects it to be far, far lower than CMS' projections.

[4] FY 2025 IPPS Final Rule. FY 2025 Estimates for New Technology Add-on Payments for Technologies Under the Traditional Pathway for FY 2025. FR 70011; https://www.govinfo.gov/content/pkg/FR-2024-08-28/pdf/2024-17021.pdf

FY 2029 Rate-Setting Methodology Changes

CMS Should Repeal the Market-Based MS-DRG Rate-Setting Methodology

CMS recently finalized a significant change to IPPS rate-setting methodology: beginning in FY 2029, CMS will calculate MS-DRG rates using the median payer-specific negotiated charges (MPSNC) that hospitals have agreed to with Medicare Advantage Organizations (MAOs).

This is the most consequential change to IPPS rate-setting since its initial creation, and one that CMS previously finalized but then repealed due to stakeholders' concerns. These concerns were not resolved in the interim between the FY 2022 repeal and last year's renewed proposal. In the CY 2026 OPPS final rule section that discussed comments received, CMS acknowledged that "*the vast majority of commenters were opposed to the proposals*."[5] Yet, the agency did nothing to substantively address the objections voiced by stakeholders, including ASTCT.

ASTCT feels strongly that the proposed methodological rate-setting change should not be implemented unless and until CMS takes the time to address the concerns raised by commenters, and provide more details on both the methodology and its projected impact.

The FY 2027 IPPS Proposed Rule Is Silent on a Major Change That Takes Effect in Two Years

ASTCT was surprised and remains concerned that the FY 2027 IPPS proposed rule contains no discussion of the methodology change or the steps CMS will take to prepare hospitals and stakeholders for its implementation. Given the scale and complexity of this change, ASTCT expected the FY 2027 IPPS proposed rule to at least include a summary of the change; an estimate of when CMS plans to share the data being collected; a way for hospitals to seek clarification on methodological questions related to the data-reporting requirement; a list of implementation timelines; and an acknowledgment of the significant stakeholder concerns raised during the CY 2026 OPPS comment period. The absence of any such discussion in the proposed rule is troubling. Further, it leaves hospitals with no meaningful opportunity to understand and raise additional questions about how the methodology will function before it is implemented.

ASTCT requests that CMS include a full summary of the final decision from the CY 2026 OPPS FR, along with any substantive updates since the publication of that rule so that the historical record of IPPS rulemaking reflects the implementation of such a significant methodological change.

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[5] CY 2026 OPPS Final Rule, 90 FR 54020

CMS has Previously Repealed this Proposal Based on Provider Concerns

This is not the first time that CMS has proposed to shift MS-DRG rate-setting to a market-based methodology anchored in MA-negotiated rates. CMS finalized a substantially similar proposal in the FY 2021 IPPS final rule, then repealed it in the FY 2022 IPPS final rule after concluding that the agency needed to: "*further consider the questions raised regarding the ability of the payer-specific charges negotiated between hospitals and MAOs to represent market-based pricing given the relationship between Medicare FFS and MAO rates*."[6] CMS also said it would consider potential alternative approaches.

The ASTCT greatly appreciates CMS' reconsideration and repeal of the finalized policy, which demonstrated agency's understanding of the vast number of technical concerns raised by the provider community. That is why ASTCT is both confused and concerned that CMS is resurfacing this proposal. We are particularly concerned by the fact that the agency did not address the issues raised by stakeholders during the FY 2021 cycle, which prompted the FY 2022 repeal. ASTCT notes that these concerns were reiterated by MedPAC in its CY 2026 OPPS comment letter, stating: "*using MA rates to set Medicare FFS MS-DRG relative weights would be largely circular as there is ample literature showing that MA plans generally set their rates for inpatient hospital services as a percentage of FFS Medicare payments.*"[7]

ASTCT strongly agrees with MedPAC's assessment. In CY 2026 rulemaking, CMS responded to the circularity concern by asserting that the current correlation between MA and FFS rates does not preclude the data from reflecting market-based pricing "*over time*."[8] ASTCT believes it is misguided for CMS to implement the FY 2029 changes to IPPS rate-setting that were finalized in the CY 2026 OPPS final rule on the basis of uncertain projections and a hope that outcomes will be better than feared.

ASTCT notes that CMS is *obligated* to ensure the integrity of Medicare payments. As such, we do not understand how the agency can rationalize reviving and finalizing a policy that CMS had previously repealed. It is particularly concerning that the agency is doing so without formally evaluating, in detail, the alternative approaches provided by stakeholders. For example, HFMA submitted a proposal in response to the FY 2021 proposed IPPS rule, presenting an alternative methodology for IPPS rate-setting called the "Direct Cost Model" (DCM). The DCM is based on detailed input from more than 580 hospitals and utilizes data generated from hospital cost-accounting systems. Although CMS acknowledged receipt of HFMA's and other stakeholders' proposals, the agency did provided neither a detailed discussion nor an evaluation of any of these alternative methodologies in the FY 2021 IPPS final rule.

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[6] CY 2026 OPPS final rule, 90 FR 54015

[7] https://www.medpac.gov/wp-content/uploads/2025/09/09122025_OPPS_ASC_CY2026_MedPAC_comment_SEC.pdf

[8] CY 2026 OPPS final rule, 90 FR 54022

ASTCT fundamentally believes that these proposals should be evaluated as potential rebasing alternatives to market-based rate-setting. We urge CMS to postpone implementation of *any* changes for FY 2029 until the alternative proposals have been evaluated in detail. This process should include seeking stakeholder input on those models and an evaluation of the alternatives compared to CMS' own market-based methodology.

In short, the core problems that led to the FY 2022 repeal have not been resolved. The data infrastructure required to make this methodology work reliably across the full diversity of hospital-MAO contracting arrangements does not exist in the form that CMS envisions. CMS has not accounted for these various arrangements, such as the prevalence of single case agreements for high-cost therapies, percentage-of-FFS payment structures, and value-based arrangements. Further, the fundamental structural concern is as valid today as it was in 2022: Medicare FFS rate-setting should be grounded in actual cost data, not in the outputs of private-market negotiations that are themselves largely derivative of the FFS rates CMS is trying to set.

A Market-Based Rate-Setting Methodology Will Not Resolve Reliance on the Chargemaster

In the FY 2021 proposed rule, CMS gave the following rationale for proposing the shift to market-based rate-setting: "*[r]ecognizing that chargemaster (gross) rates rarely reflect true market costs, we believe that by reducing our reliance on the hospital chargemaster, we can adjust Medicare payment rates so they reflect the relative market value for inpatient items and services.*" The agency reiterated this perspective when it revived the market-based proposal during the CY 2026 OPPS rulemaking cycle.

In response, ASTCT reiterates its objections, previously raised to CMS during both discussions: nothing about this rate-setting pivot will change CMS' reliance on the chargemaster for payment purposes. ASTCT understands that a shift to market-based rates would remove CMS' use of the national CCRs (and the inherently intertwined chargemaster rates) for rate-setting calculations. However, outlier and NTAP payments will continue to be calculated based on gross charges, even under a market-based relative weight methodology. Given the reliance of payment calculations on charges, hospitals would still need to consider CCRs in setting charges for the services and products provided to Medicare beneficiaries and other patients, since the Provider Reimbursement Manual instructs hospitals to charge all patients the same.

"Median Payer-Specific Negotiated Charge Per DRG" Does Not Equate to a Payment Baseline

As noted above, in the CY 2026 OPPS final rule summary of comments submitted in response to this proposal, CMS stated that: *"the vast majority of commenters"* were opposed to the market-based rate-setting methodology. Hospitals are correct to critique this proposal's purpose and methodology, since the MPSNC does not accurately represent what hospitals are paid by MAOs.

CMS stated that reporting the use of the MPSNC on the cost report should not be an additional burden, given that hospitals use a similar methodology to meet price transparency requirements. While this is partially correct from an operational standpoint (i.e., a value for this field exists in price transparency files) the downstream rate-setting and payment implications are wildly different in this scenario. Hospitals do have to list a value for each MS-DRG under public price transparency requirements. Yet, those values are so different from what patients see on their Explanation of Benefits documents that hospitals have been forced to create lengthy website content explaining that payer-specific negotiated charges bear little-to-no resemblance to what any individual payer or patient will actually pay.

In CMS' original discussion of a shift to a market-based methodology in the FY 2021 proposed rule, the agency proposed an alternative to the MPSNC: a median negotiated reimbursement amount. This alternative was described as: *"the amount the hospital received as payment for the services rendered for a patient discharge, and for which the hospital negotiated payment with a third-party payer, including a MA organization."* CMS stated that it considered this alternative because a payment of this type *"is an amount that may take into consideration the actual and final payments… as compared to a standard charge."*

CMS was astute to consider these nuances, given the range of payment methodologies that hospitals and MA plans utilize. The content of this section references complex payment agreements, including: base amounts, negotiated discounts (i.e., percent off) gross charges, New Technology Add-on Payments, outlier provisions, stoploss thresholds, and other payment provisions.

In the FY 2021 final rule, CMS finalized the more simplified MPSNC option rather than the reimbursement amount. The problematic nature of this simplification was part of the reason that CMS repealed the rate-setting shift in its next rule-making cycle. CMS did not revisit this proposed alternative in the CY 2026 OPPS discussion, and the issue remains: the MPSNC will not represent the true payments hospitals receive from MAOs. For this reason, it should not be the basis for FFS rate-setting.

In its comment to CMS on the CY 2026 OPPS proposed rule, MedPAC also identified specific distortions that the MSPNC-based methodology would introduce. MedPAC concluded its letter with a strong statement:

> *"[t]he proposal could therefore decrease the accuracy of measuring the relative costliness of providing different inpatient services to Medicare beneficiaries, while increasing the burden on hospitals and CMS. The proposal may also provide hospitals incentives to alter their contracts with MA plans to influence MS–DRG relative weights*

(such as through negotiating higher reported prices for certain inpatient services, coupled with refunds outside of the reported price)."[9]

This comment highlights the issue of trading one set of problems for another via this methodology switch rather than resolving the current system's identified problems. The market-based methodology for new and emerging treatments (like cell and gene therapies) has additional problems. Payment arrangements between hospitals and MA plans often incorporate additional payment provisions for therapies with NTAP status. They may also use a Single Case Agreement (SCA) or Single Payment Agreement (SPA) to financially protect both parties while they learn about new technologies' costs and resource uses.

The therapies mapped to MS-DRG 018 provide a suitable example: it would be impossible to use a single negotiated rate given the broad range of therapies, clinical episodes, and price points within the MS-DRG. No reported rate would be representative of how individual cases are paid. CMS' new rate-setting methodology does not account for the use of contracting mechanisms employed with new therapies, which will be exceptionally problematic as providers look to use innovative technologies to treat Medicare beneficiaries.

Medicare Advantage Data are Skewed and Incomplete

CMS' proposal presumes that hospitals are contracted with all or most of the MA plans in their geographic areas, and vice versa for MAOs. This is incorrect. Hospitals are declining to renew their contracts with MA plans due to inadequate reimbursement or issues with payment delays and cumbersome prior authorization processes.[10] A recent report found that 21 health systems have dropped their MA contracts thus far in 2026.[11] Hospitals are not single-sided in this decision-making, and payers may drop health systems for budgetary or other reasons, as well. There are no MA network adequacy requirements for the specialized care that ASTCT members provide, like stem cell transplant, gene therapy, and CAR-T. As a result, many MAOs do not have an in-network option for this care. When beneficiaries seek the care they need out-of-network, the hospital and MAO create an SCA/SPA for that patient's clinical care. These data, as stated above, will not be included in CMS' new rate-setting methodology.

As hospitals exit MA networks, the pool of negotiated charge data that CMS collects will become increasingly skewed toward hospitals that have the least leverage in a given market and/or provide a more standard set of clinical services. The remaining data will not be representative of the full range of hospitals providing inpatient care to Medicare beneficiaries.

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[9] Medciare Payment Advisory Commission. CY 2026 OPPS Comment Letter, September 12, 2025. https://www.medpac.gov/wp-content/uploads/2025/09/09122025_OPPS_ASC_CY2026_MedPAC_comment_SEC.pdf
[10] The Minnesota Star Tribune. HealthPartners leaving UnitedHealthcare's Medicare Advantage Network. https://www.startribune.com/healthpartners-unitedhealthcare-medicare-advantage-network/600383827
[11] Becker's Hospital Review. 21 health systems dropping Medicare Advantage plans - 2026 https://www.beckershospitalreview.com/finance/16-health-systems-dropping-medicare-advantage-plans-2026/

Further, the relative weights derived from these data will reflect that skewing that, over time, will exacerbate the issue and drive more providers out of MA participation. In other words, if 10 hospitals in a tri-state area provide access to cell and gene therapies but only 2-3 hospitals have contracts with MA plans for these therapies, the data that will be reported and used for rate-setting will not be representative of the costs.

In addition, CMS has not provided adequate clarity on the mechanics and review for accuracy of the data the agency will collect, nor explain how the data will be made available for stakeholder review. ASTCT requests that CMS answer the following questions to enable providers and stakeholders to better understand the agency's methodology:

- Can CMS confirm that its reference to "*median payer-specific negotiated charge*" corresponds to the 835i remittance data reported in the machine-readable file used for price transparency reporting?
- Can CMS explain what data that underly the market-based rate-setting calculations the agency will make available to stakeholders, and when this will happen?
- Does CMS have claims data from MA beneficiaries to release to the public in the same manner it makes FFS claims available in MedPAR and the Standard Analytic File?
- Does CMS plan to compute relative weight using FFS data only, MA data only, and all claims combined so stakeholders can see the relative weight variations across data sets?
- Will the 10% cap on annual relative weights' decrease remain in place?
- Is CMS planning to adjust for low-volume facilities and/or regional differences?
- Will CMS provide summarized information similar to what it does for FFS claims in its AOR/BOR files today?

Without transparency of the underlying data and CMS' calculations, stakeholders will have no way to meaningfully assess whether the resulting relative weights accurately reflect resource utilization.

ASTCT Continues to Urge a Study of Including MA Shadow Claims in Rate-setting

In 2025, more than half of Medicare beneficiaries were enrolled in MA plans, an increase from just 19% in 2007.[12] Accordingly, the past several years, ASTCT has encouraged CMS to incorporate MA claims into IPPS rate-setting. But, instead of accepting our suggestion and making a methodological change in a stepwise manner, CMS finalized a drastic change to move to a market-based relative weight methodology based only on MA negotiated charges. This change does not solve the representational problem raised by ASTCT; in fact, it replaces one incomplete dataset with another that is less reliable and more susceptible to distortion.

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[12] KFF.org. Medicare Advantage in 2025: Enrollment Update and Key Trends. https://www.kff.org/medicare/medicare-advantage-enrollment-update-and-key-trends/

ASTCT reiterates its request that CMS incorporate the claims that hospitals submit to their MACs for MA patients (known as "shadow claims") alongside FFS data for rate-setting purposes. This approach would allow CMS to better understand the costs of delivering care to all Medicare beneficiaries, not just those who are enrolled in FFS. Shadow claims are actual encounter records in the same format as FFS claims, and we believe that CMS already has access to this data. Including shadow claims would make rate-setting more statistically robust, more representative of actual resource utilization, and more reliable for low-volume MS-DRGs (like those covering stem cell transplantation and cellular therapy). Conversely, small FFS case counts create instability in year-over-year relative weights.

In the FY 2025 MedPAR file used for FY 2027 rate-setting, at least 1,089 cases were removed from the data because the claims were associated with MA patients. That number is roughly 73% of the total FFS claims used for rate-setting. Including these shadow claims would make the process more statistically robust and more representative of actual resource utilization across the full Medicare population. The market-based methodology moves in the opposite direction, substituting unreliable negotiated payment rates for a more comprehensive and representative data set. ASTCT continues to urge CMS to evaluate whether an alternative, such as the inclusion of MA shadow claims in CMS' rate-setting, would better help CMS understand the full range of costs associated with treating beneficiaries.

Conclusion

ASTCT appreciates the opportunity to provide comments on the FY 2027 IPPS proposed rule and thanks CMS for its ongoing engagement with our organization on the complex payment, coding, and reimbursement issues that affect our members and the patients they serve. The issues raised in this letter reflect ASTCT's sustained commitment to ensuring that Medicare payment policy keeps pace with the rapid evolution of cell and gene therapies, and that hospitals that provide these life-saving treatments to Medicare beneficiaries can continue to do so on a financially sustainable basis.

ASTCT welcomes the opportunity to meet with CMS 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 and Payer Relations, at mford@astct.org, with any questions or to arrange a meeting.