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This document contains submitted ASTCT comments and selections from CMS' responses in the FY 2027 IPPS Final Rule, dated July 31, 2026. As such, the Executive Summary has been removed from this version.

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.

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This document contains submitted ASTCT comments and selections from CMS' responses in the FY 2027 IPPS Final Rule, dated July 31, 2026.

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.

CMS Response: *For the same reasons, we also disagree with establishing additional flexibilities specifically for cell and gene therapies, including starting the newness date with the first administration or extending new technology add-on payment to five years.* [Comment provided during CMS discussion of a NTAP application; please see that section of the letter for more information.]

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 Response: CMS did not respond to this request.

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.

CMS Response: CMS did not respond to this request.

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.

CMS Response: CMS did not respond to these requests.

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****."*[1] *[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 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

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

calculate payment is based on the hospital's overall CCR from two fiscal years prior (this has been deemed a "lagging CCR" by HFMA[2]) 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 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

[2] 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/

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.

CMS Response: ***Comment:*** *A commenter cautioned that the base payment rate for MS-DRG 018 remains insufficient to cover the actual costs of CAR T-cell and other cellular immunotherapies, raising concerns about long-term Medicare beneficiary access. Additionally, commenters urged CMS to explore improvements to the base payment rate and consider separating cellular therapies from the broader Drugs and Cellular Therapies cost center, given the agency's own recognition of the distinct differences between traditional drugs and autologous cellular therapies.*

Response: *We appreciate commenters' support for our proposal. With respect to the request that CMS conduct outreach and education regarding the transition to the use of the condition codes, we note that when condition code ZD was implemented with CR 14247, an MLN article was published to educate providers on the requirement to report when they do not purchase the CAR T-cell therapy or other immunotherapy product in the usual manner. Therefore, we do not believe additional outreach and education is necessary at this time, but we will continue to monitor whether this might be necessary in the future.*

With respect to the request that CMS publish the details regarding specific cases, we note that information on obtaining the MedPAR Limited Data Set is available on the CMS website, at https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-forOrder/LimitedDataSets/MEDPARLDSHospitalNational. In response to comments about payment adequacy and the request to create a separate cellular therapy cost center, we refer the reader to the FY 2022 final rule (86 FR 44965), where we responded to similar comments. We will take these comments into consideration for future rulemaking as appropriate depending on how this clinical area continues to evolve.

After consideration of the public comments we received, we are finalizing our proposals without modifications regarding the calculation of the relative weight for MS–DRG 018. [Additional text available on page 49676]

CMS discussion of an MS-DRG 018 mapping request: While ASTCT did not provide comment on the discussion of a request to map the ICD-10-PCS codes for a cellular therapy used to treat Type 1 Diabetes to MS-DRG 018, we are including the text from CMS's response as it is broadly applicable to MS-DRG 018 and future mapping requests.

As discussed in the proposed rule, in reviewing this request, we noted the underlying intent of this request was to change the MS-DRG assignment of procedure code XW033DA from MS-DRGs 673, 674, and 675 to MS-DRG 018. In regard to the reassignment of procedure code XW033DA to MS-DRG 018, we

noted that the category of cell and gene therapies continues to evolve. As discussed in prior rulemaking (90 FR 36554 through 36560), we are 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 MSDRGs. We continue to examine these complex issues in consideration for future rulemaking. We acknowledge that there may be distinctions to account for as we continue to gain more experience in the use of these therapies and have additional claims data to analyze. We stated we believe this topic, relating to the administration of donislecel-jujn (Lantidra™), an allogeneic (donor) pancreatic islet cellular therapy, is appropriately aligned with and should be considered as part of that broader effort.

Therefore, for the reason discussed, we proposed to maintain the current designation of procedure code XW033DA as "non-O.R. affecting the MS-DRG" for FY 2027.

Comment: *Commenters supported CMS' proposal to maintain the designation of procedure code XW033DA as "non-O.R. affecting the MS-DRG" for FY 2027.*

Response: *We appreciate the commenters' support.*

Comment: *While not taking a position on the O.R. or non-O.R. designation of ICD-10PCS code XW033DA, several commenters stated that this proposal provided an opportunity to raise an ongoing, structural concern as they believe that CMS lacks a transparent, predictable, and clinically coherent framework for determining which cell and gene therapies map to MSDRG 018 (Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies) versus other MS-DRGs, which makes it difficult for manufacturers and academic medical centers to anticipate MS-DRG mapping, complicates economic modeling, and creates payment volatility that ultimately affects patient access. These commenters urged CMS to develop and publish, through notice-and-comment rulemaking, prospective criteria for assignment to MS-DRG 018 as the cell and gene therapy product landscape continues to expand and recommended that CMS solicit public input on the broader assignment of cell and gene therapies into the MS-DRG system to improve Medicare inpatient payment for other existing and future cell and gene therapies as the field evolves.*

Response: *We thank commenters for sharing their views and recommendations. We will take the commenters' feedback into consideration in future policy development. As discussed in the FY 2027 proposed rule, and in prior rulemaking (90 FR 36554 through 36560), we are 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. We continue to examine these complex issues in consideration for future rulemaking. After consideration of the public comments received, we are finalizing our proposal to maintain the designation of procedure code XW033DA (Introduction of donislecel-jujn allogeneic pancreatic islet cellular suspension into peripheral vein, percutaneous approach, new technology group 10) as "non-O.R. affecting the MS-DRG", for FY 2027. We refer the reader to the discussion in section II.C.6.b. of this final rule, regarding the finalized modifications for cases currently mapping to MS-DRGs 673, 674, and 675, effective October 1, 2026, for FY 2027. [FR 49641]*

CMS discussion of MS-DRG modification requests: While ASTCT did not provide comment on these issues, we are including selected text from CMS's response as it is broadly applicable to MS-DRG modification requests.

***Preamble**: As we have discussed in prior rulemaking, we may not be able to fully consider all of the requests that we receive for the upcoming fiscal year. We have found that, with the implementation of ICD-10, some types of requested changes to the MS-DRG classifications require more extensive research to identify and analyze all of the data that are relevant to evaluating the potential change.*

As discussed in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36550), beginning with FY 2027 rulemaking, we are no longer summarizing in the proposed and final rules those requests that are not able to be considered for the upcoming FY. We noted that requests that require more extensive analysis may include those involving multiple MS-DRGs, overlapping logic across multiple Major Diagnostic Categories (MDCs), special logic such as diagnosis codes combined with procedure codes, and/or complex logic including code clusters or multiple logic lists. In December 2025, we informed requestors via MEARIS™ if their MS-DRG classification change request was not able to be considered with the FY 2027 rulemaking cycle.

***Comment:** A commenter (technology association) acknowledged the process that CMS utilizes for accepting MS-DRG requests via MEARIS™ and that some types of requested changes to the MS-DRG classifications require more extensive research to identify and analyze all the data that are relevant to evaluating the potential change.*

The commenter stated that CMS notified requestors via MEARIS™ if their MS-DRG classification change request was not able to be considered with the FY 2027 rulemaking cycle and they understood that several of their members received such notifications. The commenter also stated that the agency does not publicly disclose the number of MS-DRG applications they receive and review annually. The commenter encouraged CMS to provide greater transparency regarding the overall volume and the nature of the MEARIS™ requests that are submitted to CMS each year. The commenter stated their belief that it is important for CMS to provide transparency into the number of requests that it receives each year to provide stakeholders with an understanding of the volume of requests and potential likelihood of not having their application reviewed in rulemaking the same rulemaking cycle. The commenter further stated that for those applications CMS has stated require additional analysis, CMS should provide the applicant with an expected timeline for review. According to the commenter, absent a clear process for revisiting deferred requests, stakeholders are left without clarity as to when such submissions will receive further consideration. The commenter stated it is important for CMS to establish a transparent timeline for re-evaluation of MS-DRG requests that are not addressed in the year of submission. The commenter stated they identified two circumstances in which the public comment process could function as a necessary supplement to MEARIS™. In the first example, the commenter stated that when an MS-DRG classification change request has been submitted through MEARIS™ and CMS has been unable to address the request, CMS should recognize the public comment process as an appropriate vehicle for stakeholders to consider the request. The commenter stated they agree that any policy change responsive to public comments, where CMS has not separately proposed the requested change in rulemaking, is appropriately reserved for proposal and finalization in the subsequent rulemaking cycle. The commenter stated this option would be consistent with the agency's general practice for off-cycle

ambulatory payment classification, transitional pass-through, and new technology add-on payment determinations. According to the commenter, using this approach would allow the public comment process to operate as a transparency and queue-management mechanism, not as a substitute for proposal and finalization.

In the second example, the commenter stated that when CMS has proposed to discontinue the new technology add-on payment for a specific technology, by listing that technology in a designated table within the proposed rule, the agency has put that technology's payment treatment before the public for comment. The commenter stated that the proposed new technology add-on payment discontinuation is itself the proposal. According to the commenter, any public comments addressing the adequacy of the MS-DRG payment for that technology, and a proposed corresponding adjustment to payment when the new technology add-on payment expires, are directly responsive to the action CMS has put before the public; they are not freestanding reassignment requests outside rulemaking. The commenter asserted that MS-DRG assignment is inseparable from the new technology add-on payment action that CMS has proposed. The commenter urged CMS to recognize that for the technologies subject to this scenario, any public comments that include concerns regarding payment adequacy are within the scope of rulemaking and may be considered for action in the same final rule that finalizes a proposed discontinuation of new technology add-on payment. The commenter stated that recognition of these two categories of examples would not displace MEARIS™ as the agency's submission process but could ensure that the public comments function as a supplement because exclusive reliance on MEARIS™ produces outcomes inconsistent with payment accuracy, beneficiary access, and administrative efficiency. The commenter urged CMS to address the public comments submitted for either example to include the requests received, a summary of the supporting evidence, and an explanation of the disposition.

Response: *We appreciate the commenter's feedback. In response to the commenter's recommendation that CMS provide greater transparency into the number of requests that it receives each year to afford stakeholders a better understanding of the volume of requests received and the potential likelihood of not having an application reviewed in rulemaking during that same rulemaking cycle, we note that, until the current FY 2027 rulemaking cycle, all prior MS-DRG classification change requests received via MEARIS™ since FY 2024 rulemaking have been reflected in the annual IPPS/LTCH PPS rulemakings; therefore, stakeholders were provided with details regarding the number and the nature of the MS-DRG classification change requests. We no longer believe that providing an annual summary as part of the annual rulemaking that outlines the number and nature of MS-DRG classification change requests received and for which we are unable to address for the upcoming fiscal year is beneficial because, as reflected in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36550 through 36552), we received public comments in response to such summaries that were included in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18012), urging CMS to finalize changes for requests that we had indicated we were unable to consider for FY 2026 and for which we did not propose a change to the logic for FY 2026. Additionally, providing an annual summary detailing the number and nature of MS-DRG requests received may not completely reflect the complexity of a given request.*

We continue to believe that we provide sufficient transparency through our established annual notice and comment rulemaking process. We note that, since the implementation of MEARIS™ for the submission of MS-DRG classification change requests, we have continued efforts towards refining our process for MS-DRG classification change requests. For example, as stated in the FY 2026 IPPS/LTCH PPS

final rule (90 FR 36549 through 36550), and the preamble of the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19322) and this final rule, beginning with FY 2027 rulemaking, we inform requestors via MEARIS™ if an MS-DRG classification change request is unable to be considered with the upcoming fiscal year's rulemaking cycle and that we will no longer summarize in the proposed and final rules those requests that are not able to be considered for the upcoming fiscal year. As the commenter acknowledged in its submitted comments, several of their members received such notifications. Specifically, we note that for those requests that were unable to be considered for FY 2027 rulemaking, the requestors received an electronic notification that their MS-DRG classification change request was being deferred for the FY 2027 rulemaking cycle; therefore, requestors were made aware that their MS-DRG classification change request was not being considered in the FY 2027 rulemaking cycle. With respect to the commenter's recommendation that CMS should provide the requestors who received notification that their FY 2027 MS-DRG classification change request was deferred with an expected timeline for review, we note that following this FY 2027 rulemaking, we intend to provide additional information to those requestors whose MSDRG classification change requests were deferred for FY 2027 regarding the status of their FY 2027 MS-DRG classification change request.

In response to the commenter's second example where they asserted that any public comments addressing the adequacy of the MS-DRG payment in connection with the proposed discontinuation of a new technology add-on payment for a specific technology, with a proposed corresponding adjustment to payment, are within the scope of rulemaking and may be considered for action in the same final rule that finalizes a proposed discontinuation of a new technology add-on payment technology, we disagree. Specifically, we note that under our established process, requests for consideration of an MS-DRG classification change must be submitted via MEARIS™ as discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28127) and final rule (87 FR 48800 through 48801). We disagree that the use of MEARIS™ produces outcomes inconsistent with payment accuracy, beneficiary access, and administrative efficiency. As reflected in our annual rulemakings, for the MS-DRG classification change requests we are able to consider, we present a summary of the requests received, the relevant MDC(s), MS-DRG(s), ICD-10-CM diagnosis and ICD-10-PCS procedure codes that are analyzed using the designated MedPAR claims data file and the proposals that are set forth based on the findings from our analysis of claims data and clinical review. In connection with our annual proposed rulemakings, we also provide a test version of the ICD-10 MS-DRG GROUPER software, supplemental mapping files, a draft version of the ICD-10 MS-DRG Definitions Manual and, effective with FY 2025 rulemaking, a draft version of the Definitions of Medicare Code Edits (MCE) Manual, and the associated proposed relative weights file so that the public can better analyze and understand the impact of the proposals included in the proposed rule utilizing these available resources. Therefore, we do not believe it would be appropriate to finalize MS-DRG classification changes in connection with the proposed discontinuation of a new technology addon payment for a specific technology in the absence of providing our standard data analysis and corresponding resources that are made publicly available under our established rulemaking process.

To provide further transparency in connection with our MS-DRG request process, beginning with the FY 2028 rulemaking cycle, we intend to send notifications to requestors via MEARIS™ if their MS-DRG classification change request(s) will be considered with a status update of "Under Review", and for those MS-DRG classification change requests that are unable to be considered for the upcoming fiscal year's rulemaking, we intend to send notifications to requestors via MEARIS™ with a status update of

"Deferred", followed by additional communication as to why the request is unable to be considered for the upcoming fiscal year's rulemaking cycle. Consistent with our process for the FY 2027 MS-DRG classification change requests, we intend to notify requestors by mid-December if their request is or is not able to be considered for the upcoming fiscal year.

Interested parties should submit any MS-DRG classification change requests, including any comments and suggestions for FY 2028 consideration by October 20, 2026, via MEARIS™ at: https://mearis.cms.gov/public/home. As noted, we will inform requestors via MEARIS™ if the MS-DRG classification change request is or is not able to be considered with the upcoming fiscal year rulemaking cycle. [FR 49580]

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.

Note: CMS's discussion of this section was lengthy and complex. ASTCT has selected key text sections below but encourages stakeholders that need to understand this issue to read the section in its entirety.

CMS Response: ***Comment:*** *Some commenters asserted that the accumulated cost statistic is a longstanding, simplified, and acceptable method for allocating overhead, and that CMS is departing from it without justification. Some commenters asserted that the proposal conflicts with the 42 CFR Part 413 cost-apportionment principles and Medicare's reasonable cost statute's recognition of both direct and indirect costs actually incurred. Some commenters also expressed that CMS's proposed codification of § 413.24(d)(8), Improper allocation of overhead prohibited, and the two methods providers can use to adjust the accumulated cost statistic, the Negative Adjustment Method and the Componentizing Method, represents a new prescriptive policy rather than a clarification of existing rules, is vague and would allow contractors to second guess providers' legitimate cost allocation decisions. A few commenters asserted that the Provider Reimbursement Manual does not reflect the policies CMS proposes to clarify and codify. Several commenters cited an increase in providers' administrative burden, including the burden to track purchased services if the proposals are finalized.*

Response: *We disagree with commenters' assertions that CMS is departing from using the accumulated cost statistic as a valid and accepted allocation basis under Medicare's longstanding cost-finding principles. We also disagree that the cost allocation principles set forth in our proposed codification of § 413.24(d)(8) are new or vague. Our proposal is designed to prevent cost-shifting, and enforce Medicare's longstanding, fundamental cost-finding requirements, as set forth in § 413.24 and cost reporting instructions, that any statistical basis must reflect a causal and beneficial relationship between the cost center and the overhead being allocated. Additionally, as we discussed in the proposed rule (see 91 FR 19745-46), the*

allocation principles which we proposed to codify at § 413.24(d)(8) are long-standing and have been set forth collectively in statute, regulations and various sections of the Provider Reimbursement Manual.

…Using the accumulated cost statistic has always required the provider to demonstrate a causal and beneficial relationship between the cost and the overhead being allocated. The accumulated cost statistic is not being abolished in this proposal.

…Our proposal to codify these allocation principles and instructions into the regulations does not convert them into new policy. CMS is simply proposing, through notice and comment rulemaking, to clarify and codify the longstanding statutory reasonable cost principles regarding certain cost reporting instructions into regulatory text to prevent cost shifting and to ensure uniform compliance across all provider types, and greater legal certainty for providers, and contractors. We appreciate commenters' sharing their concerns regarding an increase in administrative burden to providers, however, as previously stated, we proposed to codify into the regulations at new § 413.24(d)(8) longstanding instructions on the proper allocation of overhead costs. We believe these proposals enforce the causal and beneficial relationship of properly proportioning a provider's costs to overhead expense that is fundamental to Medicare's reasonable cost principles. [FR 50295–50302]

***Comment:** Many commenters disagreed with the proposal that requires providers to remove purchase costs from the accumulated cost statistic used to allocate A&G costs and said that CMS has presented no evidence to show that including purchased services and supplies in the accumulated cost statistic results in improper Medicare payments. Many commenters asserted that hospitals still incur their own A&G costs (contracting, legal, procurement, compliance, accounts payable, etc.) related to purchased services and therefore should not be excluded from the allocation base. Commenters suggested that removing purchase costs from the accumulated cost statistic could require removing nearly half of hospital costs and create a new Worksheet B-1 information collection requiring PRA review. Some commenters asserted that CMS has not considered the possibility that exclusion of purchased services and supplies could increase aggregate Medicare expenditures, while other commenters noted that alternative allocation bases such as square footage, salaries, and FTEs already understate overhead for items such as organ acquisition costs and CAR-T cell therapies, and the overall reimbursement impact may be immaterial…*

***Response:** We understand commenters' desire to continue to include purchase costs in the accumulated cost statistic, however, in the proposed rule we explained, with an example, how including purchased services and supplies in the accumulated cost statistic can result in improper Medicare payments. We would like to clarify that we are not requiring all purchased service costs be removed from the accumulated cost statistic. Instead, we are referring to purchased services provided under contract that should be removed from the accumulated cost statistic. The purpose of an accumulated cost statistic is to measure internal resource utilization. Contract services are performed by the external/supplying parties and the purchased contract amount does not represent the hospital's own resource consumption and therefore, the purchase contract amount should not influence how the hospital's overhead costs are distributed. We would also like to clarify that we are not requiring all supplies be removed from the accumulated cost statistic. For supplies, we are referring to supplies such*

as organs, donor tissue, blood products, and CAR-T, that are acquired on behalf of a patient and passed directly to the payer without markup, including costs that are highly variable and not representative of routine costs reimbursed separately outside of standard DRG/APC rates, and costs the hospital acquires or procures on a case-by-case basis that are not stocked routinely. Inclusions of these types of costs significantly skew CCRs and cost allocation. Our position is based, in part, on the structural logic of the cost allocation methodology. We have reviewed publicly available cost report data from multiple provider types and identified systematic misallocation resulting in inflated Medicare payments. We understand that providers may, in certain circumstances, incur a limited amount of A&G costs related to purchased services (for example, contract management, legal review, procurement, accounts payable processing, etc.), however, the provider's A&G costs related to contract management, legal review, procurement, and accounts payable processing are already captured in the provider's A&G cost center and are allocated to departments that have a genuine causal relationship to those functions. Our proposal does not prevent providers from recovering these administrative costs. Instead, it prevents these administrative costs from being disproportionately amplified by the high dollar value of purchased services or products. The issue is one of proportionality and accuracy. Additionally, the cost report framework under PRM § 4013 is designed to allocate A&G costs based on a proxy that reflects the relative consumption of administrative resources. Including purchased services and supplies in the accumulated cost statistic inflates the statistical base of cost centers that do not meaningfully consume A&G resources on an ongoing operational basis, thereby diluting the allocation to cost centers that do. Our position is that the accumulated cost statistic should reflect costs that are genuinely driven by, and benefit from, the A&G cost center, a standard that purchased services and supplies do not meet to the same degree as direct labor and operational costs. We believe that purchased services and supplies, by definition, represent costs that have already been externally administered by a third-party vendor or contractor. The purchase price paid to an OPO for purchased organs or to a CAR-T manufacturer, for example, already includes that external entity's full overhead and profit. When a hospital includes the full purchase price in its accumulated cost statistic, it is effectively using the external entity's overhead as a lever to pull the hospital's own A&G overhead into the purchased-service cost center which we believe results in a clear and demonstrable double-counting of overhead and is inconsistent with Medicare's reasonable cost principles. We also note that § 413.24(d)(6), Provider-based entities and departments: Preventing duplication of cost, already provides specific requirements for purchased services including the requirement that they be removed and separately identified for appropriate cost allocation that does not result in overallocation and improper Medicare payment to the provider. [FR 50295–50302]

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[3], respectively; ASTCT does not know the actual number but suspects it to be far, far lower than CMS' projections.

Note: CMS's discussion of this section was lengthy and complex. ASTCT has selected key sections below but encourages stakeholders that need to understand this issue to read the section in its entirety.

CMS Response: ***Comment:*** *Commenters were also specifically concerned about the effect of the proposal on cell and gene therapies. Commenters requested that given the unique patient timelines and manufacturing dynamics of autologous gene and cell therapies, CMS should maximize the new technology addon payment effective duration by starting the clock on newness following the first administration billed to Medicare and by adopting a three-year new technology add-on payment and use the agency's exceptions and adjustments authority to extend new technology add-on payment for an additional two years for these technologies. A commenter also stated that CMS could combine data from all three new technology add-on payment data years in the case of low-volume data signals or examine projections of new technology add-on payment therapy use against claims data to assess whether additional time for data collection under new technology add-on payment is needed. The commenter stated that, for example, CMS listed that it expected exagamglogene autotemcel and lovotibeglogene autotemcel to be used in 117 and 40 cases in FY 2025, respectively; it did not know the actual number but suspected it to be far, far lower than CMS' projections. A commenter stated that when assuming a three-year new technology add-on payment eligibility period and given the two-year time lag in the data*

[3] 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

that CMS uses for ratesetting, the number of claims that will exist in the data by the second year of new technology add-on payment 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. Another commenter stated that while the assignment of a billing code is a necessary condition for capturing claims data, the regulation expressly recognizes that the timing of data availability — not merely the existence of a code — is central to determining the newness period. The commenter stated that consistent with this structure, it is appropriate to interpret the newness period as beginning when claims reflecting use of the technology first appear and data begin to accumulate, rather than when a code is first assigned but not yet used in practice. The commenter also provided additional details regarding the structural factors contributing to delayed initial claims for ex vivo gene therapies that result in a material delay between code assignment and the generation of meaningful Medicare claims data in support of its request that CMS clarify that the new technology add-on payment newness period begins when claims data reflecting use of the technology first become available. In addition, the commenter requested that CMS review and share aggregate volume and charge data for ex vivo gene therapies from the most recent year of available claims because without this visibility, it was not possible to assess whether the existing data are sufficient to inform the new technology add-on payment start date or whether alternative policy approaches are warranted. The commenter believed that sharing summary information on the number of cases and associated charge levels for ex vivo gene therapies in the most recent year of IPPS claims data would promote transparency, improve the quality of stakeholder feedback, and support more timely and accurate development of MS-DRG payment policies.

Response: *We thank commenters for their comments on our proposal. We agree with commenters that it is important to have a consistent and predictable approach when we consider a documented delay in a technology's market availability in our determination of newness. We also agree with commenters that we should maintain our flexibility to account for commercial availability delays. However, we disagree that our proposal narrows the effective eligibility window or introduces interpretive uncertainty. Under the proposal, we may consider a documented delay in the beginning of a technology's newness period due to commercial availability only until the new technology add-on payment becomes effective for the fiscal year for which the applicant applied for new technology add-on payments. We would still maintain the flexibility to consider commercial availability delays until the implementation date for the new technology add-on payment. We understand that technologies often apply for new technology add-on payments prior to receiving FDA market authorization, and must balance responsible launch planning activities with our new technology add-on payment timelines. These technologies, including those that may become available shortly after the fiscal year begins, would still remain eligible for a third year of new technology add-on payment, but would no longer inappropriately become eligible for a fourth year or beyond.*

With respect to the specific criteria that we use to identify a documented delay of commercial availability, as noted, we believe it is important to maintain flexibility regarding the range of circumstances that may be identified by a new technology add-on payment applicant as resulting in a delay in commercial availability. We make these decisions on an individual basis and in consideration of any communications with applicants while developing the proposed rule and as a part of our annual notice-and-comment rulemaking. In general, although we require sufficient information to determine a newness date based on a documented delay in the technology's availability on the U.S. market, we generally rely on the applicant's narrative of the delay. As noted, we do not consider the date of first sale

of a product, or first shipment of a product, as an indicator of the entry of a product onto the U.S. market; neither of these dates indicate when a technology in fact became available for sale. We often request additional information when it is unclear to us whether a technology was not yet available for sale or was on the market but in a limited capacity. As we have also noted, we do not believe that case volume is a relevant consideration for making the determination as to whether a product is considered "new" for purposes of new technology add-on payments. We have generally established a later newness start date resulting from a documented delay in commercial availability due to a variety of commercialization activities, for example, requiring a new capable commercial partner, acquisitions, or execution of distribution agreements.

We do not believe that this proposal should apply only for future new technology add-on payment applications, or create exceptions for specific groups of technologies. We also disagree that this proposal, taken in its totality with the policy as discussed in section II.E.7 and prior rulemaking, reflects an increasingly restrictive approach to new technology add-on payment. For example, as finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69238 through 69242) to address how the prior change in the FDA marketing authorization deadline may limit the ability of new technology add-on payment applicants to be eligible for a third year of new technology add-on payments under our general practice for determining whether to extend the payment for an additional fiscal year, we now extend new technology add-on payments for an additional fiscal year when the 3-year anniversary date of the product's entry onto the U.S. market occurs on or after October 1 of that fiscal year. Overall, we continue to maintain a flexible approach to our review of an applicant's documented delay of commercial availability and generally do not require supporting documentation to substantiate an applicant's claims. We also note that we had stated we were considering this issue as early as the FY 2026 IPPS/LTCH PPS final rule (90 FR 36667; 90 FR 36671). Applicants that anticipate a significant delay in commercial availability may want to consider whether their anticipated commercial availability date would better align with a future rulemaking cycle.

As we noted in the FY 2026 IPPS/LTCH PPS final rule (90 FR 36667; 90 FR 36671), ZEVTERA® and SAINT Neuromodulation System both asserted a date of commercial availability that occurred after the new technology add-on payment for the technology began. If we were to consider the beginning of the newness period to commence on the date of commercial availability requested by the applicants, because we now extend new technology add-on payments for an additional fiscal year when the 3-year anniversary date of a product's entry onto the U.S. market occurs on or after October 1 of that fiscal year (89 FR 69238 through 69242), the technologies would be eligible for a fourth year of new technology add-on payment in FY 2028 and FY 2027, respectively. We believe it is necessary to establish an approach to address the specific scenario where a technology may have a legitimate commercial availability delay, but its new technology add-on payment has become effective and the technology (and other technologies reported using the same codes) have become eligible for new technology add-on payment, such that otherwise the technology may potentially be eligible for the new technology add-on payment for four or more years. We believe that implementing this proposal establishes a consistent approach, which would improve predictability for stakeholders. For the same reasons, we also disagree with establishing additional flexibilities specifically for cell and gene therapies, including starting the newness date with the first administration or extending new technology add-on payment to five years. [Please see full rule text for more discussion of delays.]

We also disagree with commenters that considering a product to be "new" when it was not commercially available would skew the data collected during the new technology add-on payment period. As we stated in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58955), section 1886(d)(5)(K)(ii) of the Act establishes a period of not less than 2 years and not more than 3 years for the collection of data with respect to the costs of new services or technologies. We do not believe that 2 years' worth of data would be insufficient to inform rate-setting for the inpatient setting. In addition, although the technology that had applied for new technology add-on payment may not be on the market, it is possible that other technologies reported using the same codes may enter the market and would be eligible for the new technology add-on payment.

Our current practice is to extend new technology add-on payments without a further application from the manufacturer of a competing product (85 FR 58679). As we've noted, procedure codes under the ICD-10-PCS are not manufacturer specific; rather, they are used to describe the hospital service that was performed. If, after consulting current official coding guidelines a hospital determines that an ICD-10-PCS procedure code associated with a new technology addon payment describes the technology that it used in the performance of a procedure, the hospital may report the code and may be eligible to receive the associated new technology add-on payment (89 FR 69224). We also do not believe that case volume is a relevant consideration for making the determination as to whether a product is "new." As mentioned in previous rulemaking, consistent with the statute and our implementing regulations, a technology is no longer considered as "new" once it is more than 2 to 3 years old, irrespective of how frequently the medical service or technology has been used in the Medicare population (70 FR 47349, 85 FR 58610). As such, regardless of whether the use of the technology that had applied for new technology add-on payment or other technologies reported using the same code is frequent or infrequent in the Medicare population, we would consider the costs of the technology to be included in the MS-DRG relative weights. In addition, depending on the prevalence of a disease within the Medicare beneficiary population and the clinical factors associated with the treatments, some technologies may inherently have a minimal claim volume.

Therefore, we are finalizing as proposed that, for a technology that is not yet available for sale when its new technology add-on payment becomes effective, we will consider the newness period to begin on the date preceding the start of the new technology add-on payment for the technology. [FR 49685-49689]

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."[4] 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.

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*."[5] 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*

[4] CY 2026 OPPS Final Rule, 90 FR 54020
[5] CY 2026 OPPS final rule, 90 FR 54015

that MA plans generally set their rates for inpatient hospital services as a percentage of FFS Medicare payments."[6]

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*."[7] 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.

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.

[6] https://www.medpac.gov/wp-content/uploads/2025/09/09122025_OPPS_ASC_CY2026_MedPAC_comment_SEC.pdf
[7] CY 2026 OPPS final rule, 90 FR 54022

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*)."[8]

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.[9] A recent report found that 21 health systems have dropped their MA contracts thus far in 2026.[10] 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

[8] Medcare 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
[9] The Minnesota Star Tribune. HealthPartners leaving UnitedHealthcare's Medicare Advantage Network. https://www.startribune.com/healthpartners-unitedhealthcare-medicare-advantage-network/600383827
[10] 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/

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. 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.[11] 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

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

problem raised by ASTCT; in fact, it replaces one incomplete dataset with another that is less reliable and more susceptible to distortion.

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.

CMS Response: CMS did not respond to this request.

ASTCT appreciates CMS' review of our comments and would be pleased to engage on any technical questions the agency may have.