ASTCT
American Society for
Transplantation and Cellular Therapy

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

September 15, 2025

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency [CMS-1834-P]

Dear Administrator Oz:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to submit the following comment letter regarding the CY 2026 OPPS Proposed Rule.

ASTCT is a professional membership association of more than 3,900 physicians, scientists, and other health care professionals promoting hematopoietic stem cell transplantation (SCT) and cellular therapy through research, education, scholarly publication, and clinical standards. Our Society's clinical teams have been instrumental in developing and implementing clinical care standards and advancing cellular therapy science, including participation in trials that led to current Food and Drug Administration (FDA) approvals for chimeric antigen receptor T-cell (CAR-T) therapy and hematopoietic stem cell (HSC) gene therapies for genetic immune system and blood disorders. For more than 25 years, ASTCT members have focused on innovation in the treatment of hematologic malignancies, hematologic disorders, and other immune system diseases.

ASTCT would welcome the opportunity to meet with CMS and discuss ways to improve payment for CAR-T, SCT, and gene therapies.

If CMS has any questions regarding these comments, please contact Molly Ford, ASTCT's Director of Government and Payer Relations, at mford@astct.org.

David Porter, MD
President, ASTCT
2025-2026

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Executive Summary

ASTCT appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding the FY 2026 Outpatient Prospective Payment System (OPPS) Proposed Rule (PR). Following is a summary of our requests from this letter.

1. **Autologous Cell-based Immunotherapy and Gene Therapy Proposal**
   - ASTCT once again requests that CMS recognize the Category I CPT codes released by the American Medical Association for cell collection and cell processing services and provide separate payment for them by changing the status indicator "B" assigned to them to status indicator "S".
   - ASTCT does not support CMS' proposals to include cell collection costs in a product's payment or to treat fees associated with cell collection as price concessions, and urges the agency to refrain from finalizing any proposals associated with ASP calculation.

2. **Exclusion of Cell and Gene Therapies From the C–APC Policy**
   - ASTCT supports CMS' process of adding new HCPCS codes to the list as they are issued, as it no longer requires individual stakeholders to advocate for addition to the C–APC exclusion list when the pass-through status time period concludes.
   - ASTCT requests that CMS add HCPCS code Q2056 to the exclusions table and share a preferred process for how existing codes that are going to lose pass-through status should be placed on the exclusions list off-cycle from the rulemaking process.

3. **Method to Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)**
   - ASTCT asks that CMS abandon this proposal as further supporting data is required, it is not making accurate cross-system comparisons, and it has a lack of authority based the prior Congressional directive.

4. **Request for Information (RFI): Expanding the Method to Control for Unnecessary Increases in the Volume of Covered HOPD Services to On-campus Clinic Visits**
   - ASTCT disagrees with CMS expanding its proposed volume control method to other services, and specifically to on-campus clinic visits in the future, because the OPPS and the MPFS are vastly different payment systems.
   - ASTCT urges CMS to forgo further attempts to reduce hospital payments through site neutrality measures without first accurately comparing services and payment across MPFS and OPPS.

5. **Changes to the Inpatient Only (IPO) List**
   - If CMS finalizes phasing out the Inpatient Only List (IPO) as proposed, ASTCT requests that the agency make explicit that the clinician's judgement is the sole determining factor for whether a patient receives a procedure or service as an inpatient vs. an outpatient.
   - ASTCT also asks CMS to require Medicare Advantage plans to follow fee-for-service coverage and payment standards with respect to clinician orders for inpatient care, and to prohibit site-of-service denials for procedures that are removed from the IPO list.

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6. **Proposed Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges**
   - ASTCT does not support CMS' proposed additional changes to Hospital Price Transparency requirements for CY 2026 and asks that CMS more closely scrutinize, enforce, and penalize health plans that fail to do their part as required by law.
   - ASTCT requests that any implementation of these policies be delayed until at least CY 2027.

7. **Proposed Market-Based MS–DRG Relative Weight Data Collection and Change in Methodology for Calculating MS–DRG Relative Weights Under the Inpatient Prospective Payment System**
   - ASTCT strongly opposes CMS' proposal and requests that CMS withdraw its market-based weighting methodology. CMS should, instead:
     - evaluate incorporating Medicare Advantage shadow claims into rate-setting, and
     - work collaboratively with stakeholders to develop an inpatient payment system that more accurately reflects the resources required to care for Medicare beneficiaries

8. **Request for APC Reconfiguration and Status Indicator Changes**
   - ASTCT requests that CMS reassign CPT code 38228 for CAR-T administration from APC 5694 to APC 5242.
   - ASTCT requests that CMS recognize the CPT codes released by the American Medical Association for remote patient monitoring and change the status indicator assigned to all RPM codes from "B" to separately payable status indicator "V" or "Q1," depending on the nature of the service.

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Autologous Cell-based Immunotherapy and Gene Therapy (autoCGT) Proposal

CMS requested comments about a series of proposals related to payment for cell collection and the calculation of Average Sales Price (ASP) in the Medicare Physician Fee Schedule (MPFS) PR. ASTCT submitted our comments to CMS as part of that rulemaking process and is including a summary here due to its implications for payment within OPPS, as well.

ASTCT has repeatedly advocated for separate payment for the clinical services associated with cell collection. **ASTCT once again requests that CMS recognize the Category I CPT codes released by the American Medical Association for cell collection and cell processing services (38225-38227) and provide separate payment for them by changing their assigned status indicator of "B" to status indicator "S".**

In keeping with this view, ASTCT does not support CMS' proposals to include cell collection costs in a product's payment or to treat fees associated with cell collection as price concessions.

Providers are not typically engaged in the complexities of ASP calculations and have no knowledge of the types and scope of arrangements CMS is proposing to define as price concessions. The arrangements between a manufacturer and its distributor(s), data partner(s), and other fee-based contractors are proprietary and outside the sphere of influence for any clinical service provider. Additionally, given the personalized nature of autoCGTs, there are very few discounts available to purchasing providers, creating a situation where ASP and acquisition costs have been essentially equal.

If CMS' proposed price concession assumptions drive the absolute value of ASP+6% down significantly, providers will face a net negative impact on payment when these products are used to treat Medicare beneficiaries. Without a mechanism to understand the net impact to ASP, providers of autoCGTs are left with no choice but to protest the set of proposals in its entirety.

In its proposal to treat payment for cell collection as a price concession, CMS states that these clinical services are *"part of the COGS"* (Cost of Goods Sold) for these products. This does not make sense, since a required manufacturing step cannot also be a discretionary post-production concession to its purchase price. ASTCT suspects that CMS is making the assumption that manufacturers are paying infusing providers for cell collection and, therefore, an equivalent amount should be reduced from the ASP-based payment to the provider.

From an operationalization perspective, finalization of these proposals as written would create an astounding level of provider questions related to compliance, billing, and cost reporting. There is no feasible way to seek and receive guidance on these issues in time for a January 1, 2026 effective date.

Access to autoCGTs for Medicare beneficiaries will decrease dramatically if provider payment is forced below the costs of acquiring these unique therapies, as would likely be the case with the current proposals. ASTCT understands CMS' focus on drug pricing, but there are other ways to seek partnership with manufacturers and providers beyond implementing negative pressure on ASP methodology.

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ASTCT asks CMS to refrain from finalizing any proposals associated with ASP calculation in this year's final rule and carefully consider stakeholder feedback before proposing further adjustments in forthcoming policy cycles.

Exclusion of Cell and Gene Therapies From the C–APC Policy

In the CY 2025 Final Rule, CMS finalized a policy to not package payment for cell and gene therapies into C–APCs when those cell and gene therapies are not functioning as integral, ancillary, supportive, dependent, or adjunctive to the primary C–APC service. ASTCT continues to appreciate and support this policy. In this year's PR, CMS stated the following: "*For new cell and gene therapy products that are not integral, ancillary, supportive, dependent, or adjunctive to any C–APC primary service, we will continue to add their product specific HCPCS codes, when created, to the C–APC exclusion list*."

ASTCT supports this process improvement, as it no longer requires individual stakeholders to advocate for addition to the list when the pass-through status time period concludes.

Similarly, we ask that CMS provide more information about how stakeholders with HCPCS codes established before this practice should request their code be added to the exclusion list off-cycle from the rulemaking period so they do not have to wait a full year and risk being caught up in the standard methodology. For example, HCPCS code Q2056 for ciltacabtagene autoleucel (a CAR-T therapy) is listed in the July 2025 Addendum B file with a *, indicating a change from pass-through status (SI of "G") to a status indicator of "K." Because CMS did not include Q2056 in the proposed exclusions table published with the rule, the assignment of status indicator "K" for CY 2026 would mean the code would be subject to the standard C-APC methodology, despite it being a CGT that meets the finalized parameters for exclusion.

Therefore, ASTCT requests that HCPCS code Q2056 be added to the exclusions table and that CMS share a preferred process for how CGT stakeholders with codes about to lose pass-through status are to request being added to the exclusions list off-cycle from the rulemaking process.

Method to Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)

ASTCT understands and supports CMS' mission to ensure that care for Medicare beneficiaries is delivered in the most cost-efficient way possible. We also appreciate the agency's goals of ensuring Medicare beneficiaries, especially those who are chronically ill and receiving high levels of care, are not subject to needlessly high co-pays. **ASTCT disagrees, however, with the agency's proposal to use its authority to reduce the payment of 61 HCPCS codes that are assigned to drug administration APCs provided in excepted off-campus PBDs.**

Congress grandfathered certain off-campus provider-based departments (PBDs) under the Bipartisan Budget Act of 2015 such as those that billed Medicare for outpatient services before November 2, 2015, and created additional exemptions subsequently under the 21st Century Cures Act, such as on-campus PBDs, dedicated emergency departments, cancer hospitals, and those under construction when the law was enacted. These exemptions were in part due to Congress recognizing that the patients treated in

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these locations were different from those seen in free-standing physician offices and/or newly built or acquired locations. This proposal, if finalized, would effectively reduce the payment hospitals receive for these services to 40% of the APC rate. Therefore, CMS should not finalize applying the PFS equivalent payment rate to these locations.

ASTCT also disagrees with CMS' premise that there has been an "unnecessary increase in volume" – meaning that CMS believes that beneficiaries who can safely receive drug administration in a lower-cost setting are instead receiving services in a higher-paid setting due to payment incentives created by higher OPPS rates. This ignores multiple facts about care provision in the United States – primarily, that hospitals do not scout for patients; rather, patients are referred by physicians to hospitals and physicians order the services patients receive at certain locations based on their care needs. This typically means that hospitals treat patients who are sicker than those who are seen in physician's offices, *per physician directive*. This is especially true for drug administration services, which can be complex when administered to very ill patients with multiple comorbidities and concomitant therapies.

CMS appears to be saying that a higher OPPS rate compared to a lower MPFS rate for the same CPT code creates perverse incentives about where patients are treated. But this statement overlooks the fact that OPPS and MPFS are two different and unique payment systems. Simplistic comparisons between the two cannot be made, for several reasons. First, CMS sets OPPS rates annually, using auditable hospital cost report and claims data; MPFS rates are not updated on the same scheduled and do not use the same data sources.

Second, CMS uses packaging to develop OPPS rates, but packaging is not used for MPFS rates. This is a significant difference and cannot be overlooked. Packaging results in many items and services, including low-cost drugs and biologicals, ancillary services, lab tests, minor procedures, and more, not being paid in the hospital setting, whether on-campus, off-campus, or off-campus excepted. These services are paid separately in the free-standing physician offices, resulting in higher cumulative total payment for claims with the same services.

Third, just because the same CPT code appears on claims submitted from different settings does not mean that the services provided are identical. For example, CPT code 96413 indicates that an hour of chemotherapy infusion was provided, but it reflects different services and resources across depending on the care setting, due to the packaging methodology in OPPS. While the same OPPS payment is made to both non-excepted and excepted off-campus PBDs for CPT code 96413, CMS cannot assume that the patients being treated are clinically identical or are receiving the same type of additional services during the encounter. Just as CMS erroneously compared CPT code 96413 provided in a free-standing physician's office to hospital locations, it is once again erroneously assuming that the reduced payment being made to non-excepted off-campus PBDs should automatically be applied to excepted off-campus PBDs and that they will be able to continue to treat complex patients safely and effectively.

ASTCT asks that CMS abandon this proposal as further supporting data is required, it is not making accurate cross-system comparisons, and it has a lack of authority based the prior Congressional directive.

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Request for Information (RFI): Expanding the Method to Control for Unnecessary Increases in the Volume of Covered HOPD Services to On-campus Clinic Visits

ASTCT disagrees with CMS expanding its proposed volume control method to other services – specifically to on-campus clinic visits in the future – because the OPPS and the MPFS are vastly different payment systems. CMS' concept of packaging under OPPS as described above means a wide array of items and services are packaged when paid to hospitals but are paid separately to free-standing physician offices under MPFS.

Under OPPS, that hospitals use HCPCS code G0463 to report and describe a wide array of visit types (e.g., simple, complex, long, short, etc.). The single payment associated with G0463 under the OPPS is intended to cover this array of visits and the items and services provided by the hospital. There are many examples of packaged services that would never be paid separately in addition to the visit (e.g., an array of services with Status Indicators "N", "Q1", "Q4" procedures) where the "primary" service (e.g., SI "S" or "T") is provided, along with lots of other services which are not paid for separately. This is very different from payment to free-standing physician offices under MPFS, where items and services are paid for separately.

In contrast, physicians have an assortment of Evaluation and Management (E/M) codes and other visit codes to report services provided under MPFS, all of which have varying payment amounts to reflect the services and resources utilized. Because there is no packaging under MPFS, the visit during the patient encounter is paid for separately in addition to all the other items and services rendered to the patient.

Hospitals are already challenged by being paid a single packaged rate for all their various types of patient visits. CMS' proposal to pay only 40% of the APC rate in order to align OPPS and MPFS payment rates is completely untenable. The agency's proposal will exponentially increase the burden hospitals already face in providing comprehensive care to their patients.

ASTCT urges CMS to forgo further attempts to reduce hospital payments through site neutrality measures.

Changes to the Inpatient Only List

ASTCT understands that CMS proposes to phase out the Inpatient Only List (IPO) list over three years, beginning in CY 2026 with the removal of 285 mostly musculoskeletal services. We are in support of this change *only* if CMS is explicit that the clinician's judgement is the sole determining factor for whether a patient receives a procedure or service, as an inpatient vs. an outpatient. This is especially crucial for cell and gene therapies (CGT), given how rapidly treatments are evolving, the type and mix of patients being treated, and the limited number of specialized treatment centers that are able to provide these therapies. CGT clinicians must retain the authority to determine whether a patient receives a service as an inpatient or an outpatient. These determinations, of course, depend on the patient's needs, but also factor in the facilities' resources and capabilities. Any policy change must respect this clinical discretion.

CMS must also make clear to Medicare Advantage (MA) Plans and other payers that its elimination of the IPO list has nothing to do with the patient's status going forward. ASTCT has significant concerns

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that MA Plans, which already resist compliance with CMS' two-midnight rule for covered Part A stays, will use the phase-out of the IPO to deny legitimate inpatient claims. Without the IPO list as a compliance anchor, MA plans could more aggressively downgrade patients to outpatient or observation status. Doing so will create additional prior authorization burdens, upfront denials, concurrent review friction, and costly utilization review disputes. The outcome will be administratively burdensome and is likely to impact timely access to patient care. Therefore, ASTCT asks CMS to require MA plans to follow fee-for-service coverage and payment standards with respect to clinician orders for inpatient care, and to prohibit site-of-service denials for procedures that are removed from the IPO list.

In addition, if CMS finalizes phasing out the IPO list and simultaneously adds procedures to the Ambulatory Surgical Center (ASC) Covered Procedure List (CPL), careful monitoring of quality and patient outcomes will be essential. ASTCT is particularly concerned that ASCs may transfer high-intensity or high-risk patients that they cannot fully manage to hospitals, which could raise potential safety concerns. To ensure beneficiary safety protections, CMS should update ASC Conditions of Participation to require: 1) ASC clinicians to hold admitting privileges at the hospital to which patients would be transferred and, 2) A formal transfer agreement between ASCs and hospitals. We strongly believe that CMS must remain proactive in protecting beneficiary safety and quality during and after the IPO-phase-out.

If CMS finalizes phasing out the IPO as proposed, ASTCT requests that the agency explicitly state that the clinician's judgement is the sole determining factor for whether a patient receives a procedure or service as an inpatient vs. an outpatient.

ASTCT also asks CMS to require MA plans to follow fee-for-service coverage and payment standards with respect to clinician orders for inpatient care, and to prohibit site-of-service denials for procedures that are removed from the IPO list.

Proposed Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges

ASTCT supports price transparency policies that provide patients with clear, accurate information. We believe, however, that the proposed additional changes to Hospital Price Transparency (HPT) requirements for CY 2026 will not advance the goal of providing meaningful information so consumers can plan for the costs associated with their care.

Among the potential HPT changes, CMS proposes revisions to §180.20 to add definitions for "*tenth (10th) percentile allowed amount," "median allowed amount," and "ninetieth (90th) percentile allowed amount.*" These values would be derived from 835 electronic remittance advice (ERA) transaction data and included in machine-readable files (MRFs).

ASTCT is concerned that CMS proposes to enforce additional requirements on hospital providers, but there is no similar scrutiny, enforcement, or penalty whatsoever on health plans (i.e., the Transparency in Coverage requirements). This is further obviated by the fact that the payers (not providers) are in the best position to provide their members with accurate information about costs and responsibility at any given hospital.

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ASTCT is concerned that 835 ERA files contain data that are inconsistent with the payer-specific rates negotiated in hospital contracts. Providers commonly dispute payments because payers routinely do not pay according to their contracted rates. Payers use a myriad of payment-reduction and payment-avoidance tactics to deny and/or delay claims that are both accurate and correctly submitted. CMS' proposed use of ERA files could lead the agency to publish erroneous and false information.

Furthermore, payers are notorious for utilizing codes such as Claim Adjustment Reason Code (CARC) and Remittance Advice Remark Codes (RARC) inconsistently, both among distinct payers as well as for transactions within the same contract. Until CMS enforces HIPAA standard transaction requirements (not only for remittances, but for claims as well), the agency should not force the use of 835 ERA data.

Providers have already expended an inordinate number of resources to comply with HPT requirements. The proposed additional changes run counter to the Administration's stated desire to eliminate wasteful and administratively burdensome regulations. Finally, CMS also has not shown any evidence that consumers are using HPT data in any meaningful way.

ASTCT does not support additional changes to current HPT requirements and instead requests that CMS more closely scrutinize, enforce, and penalize health plans that fail to do their part as required by law.

Notwithstanding our objections, if CMS finalizes the proposed changes, we estimate that providers would need, at minimum, one additional year to implement any additional HPT requirements. Requiring providers to comply by the beginning of 2026 is completely impossible. **ASTCT requests that any implementation of these policies be delayed until at least CY 2027.**

Proposed Market-Based MS–DRG Relative Weight Data Collection and Change in Methodology for Calculating MS–DRG Relative Weights Under the Inpatient Prospective Payment System

ASTCT strongly opposes CMS' proposal to introduce a market-based methodology that relies on median Medicare Advantage Organization (MAO) negotiated charges. ASTCT also notes that proposing a methodology for one payment system (IPPS) within the PR of a *different* payment system (OPPS) does not reflect the intent of the annual rulemaking cycles and will not result in the amount or kind of stakeholder feedback necessary to properly evaluate a proposal.

CMS is Mischaracterizing Providers' Appropriate Practice of Following CMS' Own Charging Guidance

ASTCT is concerned with CMS' characterization and rationale for the current proposal. CMS suggests that the goal is to reduce reliance on "*highly inflated*" and "*inherently unreasonable*" hospital chargemasters that CMS claims are *"…used to secure higher payments from Medicare and private payers*." This assertion ignores decades of Medicare Cost Reporting history as well as CMS' own guidance given to providers through preamble text in various final rules as well as long-standing guidance from the *Provider Reimbursement Manual*.

For example, almost two decades ago, in the CY 2006 Outpatient Final Rule, CMS responded to commenters questions about reporting device charges by stating, *"…hospitals have the ability to set*

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charges for items properly so that charges converted to costs can appropriately account fully for their acquisition and overhead costs…."[1] CMS' perspective is repeated within the *Provider Reimbursement Manual* (Part 1, Chapter 22, Section 2203), which states, *"[E]ach facility should have an established charge structure which is applied uniformly to each patient as services are furnished to the patient and which is reasonably and consistently related to the cost of providing the services."*[2]

CMS' current proposal also overlooks the reality of IPPS payment formulas. CMS' methodology for paying providers for inpatient hospitalizations includes a process by which CMS reduces billed charges by Cost-to-Charge Ratios (CCRs) to estimate a "calculated cost." This methodology therefore requires providers to increase charges so that the payment formulas yield a reasonable estimate of actual cost. For purchased items like drugs and devices, providers essentially need to take their invoice cost and mark-up that amount by the same CCR factor that CMS will later apply, so that the payment calculation yields a final cost approximation in keeping with the provider's actual cost. In other words, if hospitals added smaller mark-ups to their true costs, CMS' estimates of their calculated costs would result in massive underpayment.

In recent years, provider concerns about the optics of setting charges in accordance with CMS' guidance have led ASTCT and others to request explicit guidance from CMS that charging practices which may appear *"inappropriate"* are, in fact, both acceptable and necessary under the agency's own methodology. This is particularly true for CGTs, due to their very high starting acquisition costs. ASTCT appreciates that CMS has responded to these comments in recent rulemaking, confirming that providers may set their charges in a manner that reflects their costs and aligns with their Cost-to-Charge Ratios (CCRs).

ASTCT has specifically sought clarification in the context of New Technology Add-On Payment (NTAP) and outlier formulas, regarding whether it is appropriate for providers to set charges based on their own CCRs. For example, if a provider has a CCR of .25 and purchases a cell therapy product for $500,000, the provider would, at a minimum (as this does not reflect overhead or handling), need to report a $2,000,000 charge so that CMS' calculation reflects the $500,000 cost. In response, CMS affirmed in both the FY 2021 and FY 2022 IPPS final rules that: *"there is nothing that precludes hospitals from setting their drug charges consistent with their CCRs."* [3,4] Additionally, the most recent guidance comes in the recently released FY 2026 IPPS Final Rule, where CMS responded to commenters questions about how to set charges by pointing them back to the long-standing guidance in the *Provider Reimbursement Manual*.

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[1] Centers for Medicare & Medicaid Services (CMS), *Medicare CY 2006 Outpatient Final Rule*, Baltimore (MD): CMS, November 10, 2005. Online: https://www.federalregister.gov/documents/2005/11/10/05-22136/medicare-program-changes-to-the-hospital-outpatient-prospective-payment-system-and-calendar-year

[2] Centers for Medicare & Medicaid Services (CMS), *Provider Reimbursement Manual, Publication 15-1 (Part 1, Chapter 22; Section 2203)*, Baltimore (MD): CMS, October 17, 2019. Online: https://www.cms.gov/regulations-and-guidance/guidance/manuals/paper-based-manuals-items/cms021929.

[3] Centers for Medicare & Medicaid Services (CMS), *Medicare FY 2021 Inpatient Final Rule*, Baltimore (MD): CMS, September 2, 2020. Online: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2021-ipps-final-rule-home-page

[4] Centers for Medicare & Medicaid Services (CMS), *Medicare FY 2022 Inpatient Final Rule*, Baltimore (MD): CMS, August 13, 2021. Online: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2022-ipps-final-rule-home-page.

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Taken together, this guidance makes clear that CMS has long expected providers to set charges in a way that aligns with the formulas. The only way for providers to remain compliant with CMS' charging requirements, while ensuring CMS' calculated cost adequately represents actual cost, is to apply a markup as described above. In other words, it is CMS' *own* charging policies that produce the appearance of "*highly inflated"* charges in hospital chargemasters.

Therefore, it is alarming to ASTCT that CMS would now criticize providers for following the aforementioned framework. This is unfair and inconsistent with the Agency's own rules. Furthermore, this framing is also dangerous, as it suggests providers are manipulating Medicare when in fact they are complying with CMS' system. To now blame hospitals or to lead the public to perceive hospital charges as "*inherently unreasonable*" is misleading and disheartening.

If CMS wishes to fundamentally alter hospital charging practices via this proposal, it must first redesign the IPPS payment formulas that rely on CCRs and revise decades of Agency policy. ASTCT has consistently urged CMS through the IPPS rule-making cycle to do exactly that: create a methodology that better accounts for novel therapies and avoids mischaracterizing compliance as abuse.

Limitations of Using MAO-Negotiated Rates & Median Allowed Amounts for MS-DRG Relative Weights

CMS' stated goal of better aligning MS-DRG relative weights with hospital resources is important, and one we share. However, relying on median payer-specific charges that hospitals have negotiated with MAOs will not advance CMS' objectives to better understand IPPS resource use for MA beneficiaries.

CMS itself acknowledges that MA rates are generally correlated with, and often directly derived from, Medicare Fee-for-Service (FFS) rates – i.e. MS-DRG-based payments. Substituting these charges is therefore essentially circular logic, replacing one Medicare-linked amount with another. This approach is unlikely to improve resource alignment overall, and any changes to weights based on this methodology could still be inappropriate and unrelated to resource use. This is primarily because MAO-negotiated rates are often shaped by market dynamics that could have little to do with actual cost. For example, hospitals may accept lower MA rates in exchange for higher commercial rates from the same payer across multiple lines of business, or they may agree to lower rates for certain MS–DRGs as part of a broader contracting strategy driven by leverage or network considerations rather than resource needs.

If CMS substitutes a "median allowed amount" when negotiated charges are unavailable, the problem worsens. Allowed amounts reflect what payers paid, not necessarily resource utilization, and are often reduced by underpayments and denials. For example, MAOs frequently fail to recognize certain billed charges for outlier or stop-loss payments even when billed through HIPAA standard transactions. Despite the fact that CMS emphasized in the 2024 MA plan year final rule that MAOs must comply with CMS coding and claims submission guidelines under HIPAA (88 FR 22198), the experience of our members is that some MAOs remain non-compliant. As a result, actual payments are commonly and significantly lower than expected, sometimes for reasons that may not comply with federal requirements. Using these figures would inject even greater inaccuracies into the weighting formula, further damaging and penalizing hospitals. Until CMS enforces adherence to HIPAA standard transactions, median payer-negotiated payment rates, cannot serve as a reliable or representative basis for MS-DRG relative weight setting.

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ASTCT requests that CMS withdraw its market-based weighting methodology and instead 1) evaluate incorporating Medicare Advantage shadow claims into rate-setting, and 2) work collaboratively with stakeholders to develop an inpatient payment system that more accurately reflects the resources required to care for Medicare beneficiaries.

Request for APC Reconfiguration and Status Indicator Changes

Request for APC Reassignment for CPT Code 38228

ASTCT requests that CMS reassign CPT code 38228 from the Level IV Drug Administration APC 5694 to the same APC used for autologous stem cell administration (5242). This change would ensure consistency in assignment and provide a payment rate that more accurately reflects the facility costs associated with outpatient administration of CAR-T cell therapy.

Like autologous stem cell transplant, outpatient CAR-T administration requires significant nurse monitoring. This is why the AMA placed CPT code 38228 in the same section of CPT as the stem cell transplant codes, rather than in the drug administration section. CMS has also recognized these similarities in the inpatient setting. Initially, ICD-10-PCS codes for the administration of several CAR-T products were assigned to the autologous stem cell transplant MS-DRGs 016 and 017, until CMS created a dedicated MS-DRG 018 for CAR-T and Other immunotherapies.

ASTCT requests that CMS reassign CPT code 38228 to APC 5242, as this would result in reimbursement to providers that more appropriately covers the resources required to administer CAR-T to hospital outpatients.

Status Indicators for Remote Physiological Monitoring

ASTCT requests that CMS recognize the hospital resources required when clinicians order and hospital staff provide remote patient monitoring (RPM) services for patients with acute and chronic conditions. Many of our immunocompromised patients, stem cell transplant patients, and cell and gene therapy patients can benefit from RPM services, but delivering these services draws on substantial hospital resources. This includes, but is not limited to, setting up devices; educating patients on their use; and monitoring data to ensure they are transmitted, received, and compiled for clinicians to use as they provide patients with ongoing care.

While we are eager to expand RPM to monitor and manage patients and improve outcomes, ASTCT is concerned that CMS' assignment of status indicator "B" may discourage providers from furnishing these services. Status indicator "B" is problematic because it signals that CMS expects hospitals to report some other code in place of the one that accurately represents the service provided. In practice, hospitals often substitute the generic clinic visit code (G0463), which is assigned status indicator "V" and has an APC payment rate. However, reporting G0463 does not accurately convey the specific service actually being provided, either to the patient on their explanation of benefits or to CMS via the claim, even though payment is received.

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ASTCT requests that CMS recognize the importance of digital health technologies and the significant role they play in advancing patient care by recognizing the actual CPT codes released by the AMA for remote patient monitoring (RPM) and changing the status indicator assigned to all RPM codes from "B" to separately payable status indicator "V" or "Q1," depending on the nature of the service.

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

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